## EXHIBIT G

## FDA Listing of Authorized Generics as of April 1, 2022

## Note:

This list of authorized generic drugs (AGs) was created from a manual review of FDA's database of annual reports submitted to the FDA since January 1, 1999 by sponsors of new drug applications (NDAs). Because the annual reports seldom indicate the date an AG initially entered the market, the column headed "Date Authorized Generic Entered Market" reflects the period covered by the annual report in which the AG was first reported. Subsequent marketing dates by the same firm or other firms are not included in this listing. As noted, in many cases FDA does not have information on whether the AG is still marketed and, if not still marketed, the date marketing ceased. Although attempts have been made to ensure that this list is as accurate as possible, given the volume of data reviewed and the possibility of database limitations or errors, users of this list are cautioned to independently verify the information on the list. We welcome comments on and suggested changes (e.g., additions and deletions) to the list, but the list may include only information that is included in an annual report. Please send suggested changes to the list, along with any supporting documentation to: *AuthorizedGenerics@FDA.HHS.GOV* 

## <u>A B C D E F G H I J K L M N O P Q R S T U V X Y Z</u>

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1	ACANYA	Gel	1.2% / 2.5%	Bausch Health Americas, Inc.	07/2018
2	ACCOLATE	Tablets	20 mg	AstraZeneca Pharmaceuticals	11/19/2010
3	ACCOLATE	Tablets	10 mg	AstraZeneca Pharmaceuticals	11/19/2010
4	ACCUNEB	Solution	1.25 mg/3 mL	Mylan Specialty L.P.	02/2012
5	ACCUNEB	Solution	0.63 mg/3 mL	Mylan Specialty L.P.	02/2012

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
6	ACCURETIC	Tablets	10 mg/12.5 mg	Pfizer Pharmaceuticals Ltd.	02/06/2006
7	ACCURETIC	Tablets	20 mg/12.5 mg	Pfizer Pharmaceuticals Ltd.	02/06/2006
8	ACCURETIC	Tablets	20 mg/25 mg	Pfizer Pharmaceuticals Ltd.	02/06/2006
9	ACEPHEN	Suppositories	120 mg	G & W Laboratories, Inc.	Prior to 1/1/1999
10	ACETADOTE	Injection	6 g/30 mL (200 mg/mL)	Cumberland Pharmaceuticals, Inc.	1/7/2013
11	ACTICLATE	Tablets	75 mg	Almirall, LLC	02/2018
12	ACTICLATE	Tablets	150 mg	Almirall, LLC	02/2018
13	ACTIGALL	Capsules	300 mg	Allergan Sales, LLC	08/13/2003
14	ACTIQ	Lozenge	1600 mcg	Cephalon, Inc.	09/26/2006
15	ACTIQ	Lozenge	400 mcg	Cephalon, Inc.	09/26/2006
16	ACTIQ	Lozenge	200 mcg	Cephalon, Inc.	09/26/2006
17	ACTIQ	Lozenge	800 mcg	Cephalon, Inc.	09/26/2006
18	ACTIQ	Lozenge	1200 mcg	Cephalon, Inc.	09/26/2006
19	ACTIQ	Lozenge	600 mcg	Cephalon, Inc.	09/26/2006
20	ACTIVELLA	Tablets	1 mg / 0.5 mg	Amneal Pharmaceuticals LLC	01/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
21	ACTONEL	Tablets	150 mg	Warner Chilcott Company LLC	06/2014
22	ACTOS	Tablets	45 mg	Takeda Pharmaceuticals USA	08/17/2012
23	ACTOS	Tablets	30 mg	Takeda Pharmaceuticals USA	08/17/2012
24	ACTOS	Tablets	15 mg	Takeda Pharmaceuticals USA	08/17/2012
25	ACULAR LS	Ophthalmic Solution	0.4%	Allergan, Inc.	11/11/2013
26	ACZONE	Gel	7.5%	Almirall, LLC	01/2020
27	ADDERALL XR	Extended- release Capsules	25 mg	Takeda Pharmaceuticals USA Inc.	10/2016 - 10/2017
28	ADDERALL XR	Extended- release Capsules	10 mg	Takeda Pharmaceuticals USA Inc.	04/02/2009
29	ADDERALL XR	Extended- release Capsules	15 mg	Takeda Pharmaceuticals USA Inc.	04/02/2009
30	ADDERALL XR	Extended- release Capsules	10 mg	Takeda Pharmaceuticals USA Inc.	10/2016 - 10/2017

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
31	ADDERALL XR	Extended- release Capsules	5 mg	Takeda Pharmaceuticals USA Inc.	10/2016 - 10/2017
32	ADDERALL XR	Extended- release Capsules	20 mg	Takeda Pharmaceuticals USA Inc.	04/02/2009
33	ADDERALL XR	Extended- release Capsules	30 mg	Takeda Pharmaceuticals USA Inc.	04/02/2009
34	ADDERALL XR	Extended- release Capsules	20 mg	Takeda Pharmaceuticals USA Inc.	10/2016 - 10/2017
35	ADDERALL XR	Extended- release Capsules	25 mg	Takeda Pharmaceuticals USA Inc.	04/02/2009
36	ADDERALL XR	Extended- release Capsules	15 mg	Takeda Pharmaceuticals USA Inc.	10/2016 - 10/2017
37	ADDERALL XR	Extended- release Capsules	30 mg	Takeda Pharmaceuticals USA Inc.	10/2016 - 10/2017
38	ADRENACLICK	Injection	0.15 mg	Impax Laboratories, LLC	04/01/2010
39	ADRENACLICK	Injection	0.3 mg	Impax Laboratories, LLC	04/01/2010
40	ADVAIR DISKUS	Inhalation Powder	100/50 mcg	GlaxoSmithKline Intellectual Prop. Ltd. England	02/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
41	ADVAIR DISKUS	Inhalation Powder	500/50 mcg	GlaxoSmithKline Intellectual Prop. Ltd. England	02/2019
42	ADVAIR DISKUS	Inhalation Powder	250/50 mcg	GlaxoSmithKline Intellectual Prop. Ltd. England	02/2019
43	AIRDUO RESPICLICK	Powder	55 mcg / 14 mcg	Teva Branded Pharmaceutical Products R&D Inc.	04/2017
44	AIRDUO RESPICLICK	Inhalation Powder	113 mcg/14 mcg	Teva Branded Pharmaceutical Products R&D Inc.	04/2017
45	AIRDUO RESPICLICK	Inhalation Powder	232 mcg/14 mcg	Teva Branded Pharmaceutical Products R&D Inc.	04/2017
46	ALAWAY	Ophthalmic Solution	0.035%	Bausch & Lomb Incorporated	2014
47	ALAWAY	Ophthalmic Solution	0.035%	Bausch & Lomb Incorporated	2020
48	ALAWAY	Ophthalmic Solution	0.035%	Bausch & Lomb Incorporated	2020
49	ALAWAY	Ophthalmic Solution	0.035%	Bausch & Lomb Incorporated	2014
50	ALAWAY	Ophthalmic Solution	0.035%	Bausch & Lomb Incorporated	2014
51	ALAWAY	Ophthalmic Solution	0.035%	Bausch & Lomb Incorporated	2012

	<b>Proprietary Name</b>	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
52	ALAWAY	Ophthalmic Solution	0.035%	Bausch & Lomb Incorporated	2020
53	ALBENZA	Tablets	200 mg	Impax Laboratories, LLC	09/2018
54	ALBENZA	Tablets	200 mg	Impax Laboratories, LLC	unknown
55	ALDACTAZIDE	Tablets	25 mg/25 mg	Pfizer Inc.	10/06/2003
56	ALLEGRA	Tablets	30 mg	Sanofi Aventis US LLC	02/2005 - 02/2006
57	ALLEGRA	Tablets	60 mg	Sanofi Aventis US LLC	02/2005 - 02/2006
58	ALLEGRA	Tablets	180 mg	Sanofi Aventis US LLC	02/2005 - 02/2006
59	ALLEGRA-D12 HOUR	Extended- release Tablets	60 mg/120 mg	Sanofi Aventis US LLC	12/2004 - 12/2005
60	AMARYL	Tablets	1 mg	Sanofi Aventis US LLC	11/2004 - 11/2005
51	AMARYL	Tablets	2 mg	Sanofi Aventis US LLC	11/2004 - 11/2005
62	AMARYL	Tablets	4 mg	Sanofi Aventis US LLC	11/2004 - 11/2005
63	AMBIEN	Tablets	5 mg	Sanofi Aventis US LLC	12/2006 - 12/2007
54	AMBIEN	Tablets	10 mg	Sanofi Aventis US LLC	12/2006 - 12/2007
65	AMBIEN CR	Extended- release Tablets	12.5 mg	Sanofi Aventis U.S. LLC	12/2010

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
66	AMBIENCR	Extended- release Tablets	6.25 mg	Sanofi Aventis U.S. LLC	10/2010
67	AMICAR	Tablets	1000 mg	Clover Pharmaceuticals Corporation	06/01/2012
68	AMMONUL	Injection	10% / 10%	Bausch Health US, LLC	03/2017
69	AMPYRA	Tablets	10 mg	Acorda Therapeutics, Inc.	09/2018
70	AMRIX	Capsules	30 mg	Cephalon, Inc.	03/2019
71	AMRIX	Capsules	15 mg	Cephalon, Inc.	03/2019
72	AMRIX	Capsules	30 mg	Cephalon, Inc.	03/2019
73	AMRIX	Capsutls	15 mg	Cephalon, Inc.	03/2019
74	ANAFRANIL	Capsules	25 mg	Mallinckrodt	07/2015
75	ANAFRANIL	Capsules	50 mg	Mallinckrodt	07/2015
76	ANAFRANIL	Capsules	75 mg	Mallinckrodt	07/2015
77	ANAPROX DS	Tablets	550 mg	Atnahs Pharma US Limited	10/2018
78	ANCOBAN	Capsules	500 mg	Bausch Health US, LLC	01/17/2012
79	ANCOBAN	Capsules	250 mg	Bausch Health US, LLC	07/2017
80	ANGIOMAX	Powder, for injection solution, lyophilized	250 mg	Sandoz Inc.	10/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
81	ANGIOMAX	Powder, for injection solution, lyophilized	250 mg	Sandoz Inc.	02/2017
82	ANTARA	Capsules	30 mg	Lupin, Inc.	12/2020
83	ANTARA	Capsules	90 mg	Lupin, Inc.	12/2020
84	ANTARA	Capsules	43 mg	Lupin, Inc.	02/22/2013
85	ANTARA	Capsules	130 mg	Lupin, Inc.	02/22/2013
86	APADAZ	Tablets	8.16 mg/325 mg	KVK-Tech, Inc.	06/2019
87	APRISO	Extended- release Capsules	0.375 g	Salix Pharmaceuticals, Inc.	07/2018
88	APTENSIO XR	Extended- release Capsules	60 mg	Rhodes Pharmaceuticals L.P.	04/2020
89	APTENSIO XR	Extended- release Capsules	10 mg	Rhodes Pharmaceuticals L.P.	04/2020
90	APTENSIO XR	Extended- release Capsules	15 mg	Rhodes Pharmaceuticals L.P.	04/2020
91	APTENSIO XR	Extended- release Capsules	20 mg	Rhodes Pharmaceuticals L.P.	04/2020
92	APTENSIO XR	Extended- release Capsules	30 mg	Rhodes Pharmaceuticals L.P.	04/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
93	APTENSIO XR	Extended- release Capsules	40 mg	Rhodes Pharmaceuticals L.P.	04/2020
94	APTENSIO XR	Extended- release Capsules	50 mg	Rhodes Pharmaceuticals L.P.	04/2020
95	ARAVA	Tablets	10 mg	Sanofi Aventis US LLC	09/07/2015
96	ARAVA	Tablets	20 mg	Sanofi Aventis US LLC	09/07/2015
97	ARICEPT	Film coated tablets	5 mg	Eisai, Inc.	11/25/2009 - 11/24/2010
98	ARICEPT	Film coated tablets	10 mg	Eisai, Inc.	11/25/2009 - 11/24/2010
99	ARICEPT ODT	Orally disintegrating tablets	10 mg	Eisai, Inc.	10/18/2009 - 11/24/2010
100	ARICEPT ODT	Orally distinegrating tablets	5 mg	Eisai, Inc.	10/18/2009 - 11/24/2010
101	ARIXTRA	Injection	5 mg / 0.4 mL	Mylan Ireland Limited	12/2014 - 12/2015
102	ARIXTRA	Injection	7.5 mg/0.6 mL	Mylan Ireland Limited	12/2014 - 12/2015
103	ARIXTRA	Injection	10 mg / 0.8 mL	Mylan Ireland Limited	12/2014 - 12/2015
104	ARIXTRA	Injection	2.5 mg/0.5 mL	Mylan Ireland Limited	12/2014 - 12/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
105	AROMASIN	Tablets	25 mg	Pfizer Inc.	11/02/2010
106	ARTHROTEC	Tablets	75 mg/200 mcg	Pfizer Inc.	07/10/2011
107	ARTHROTEC	Tablets	50 mg/200 mcg	Pfizer Inc.	07/10/2011
108	ATACAND	Tablets	32 mg	ANI Pharmaceuticals, Inc.	05/21/2013
109	ATACAND	Tablets	16 mg	ANI Pharmaceuticals, Inc.	05/21/2013
110	ATACAND	Tablets	4 mg	ANI Pharmaceuticals, Inc.	05/21/2013
111	ATACAND	Tablets	8 mg	ANI Pharmaceuticals, Inc.	05/21/2013
12	ATACANDHCT	Tablets	32 mg/25 mg	ANI Pharmaceuticals, Inc.	09/2018
113	ATACANDHCT	Tablets	32 mg/12.5 mg	ANI Pharmaceuticals, Inc.	09/2018
14	ATACANDHCT	Tablets	16 mg/12.5 mg	ANI Pharmaceuticals, Inc.	09/2018
15	ATELVIA	Tablets	35 mg	Allergan	2015
116	ATIVAN	Injection	2 mg/mL	Baxter Healthcare Corporation	10/31/2003

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
117	ATIVAN	Injection	4 mg/mL	Baxter Healthcare Corporation	10/31/2003
118	ATRALIN	Gel	0.05%	Bausch Health Americas, Inc.	07/26/2007
119	ATRALIN	Gel	0.05%	Bausch Health Americas, Inc.	06/19/2014
120	AUGMENTIN	Oral Suspension	250 mg/62.5 mg per 5 mL	Dr. Reddy's Laboratories Inc.	10/1990
121	AUGMENTIN	Oral Suspension	200 mg/28.5 mg per 5 mL	Dr. Reddy's Laboratories Inc.	10/22/1990
122	AUGMENTIN	Oral Suspension	400 mg/57 mg per 5 mL	Dr. Reddy's Laboratories Inc.	10/22/1990
123	AUGMENTIN	Tablets	250 mg	Dr. Reddy's Laboratories Inc.	10/22/1990
124	AUGMENTIN	Tablets	500 mg	Dr. Reddy's Laboratories Inc.	10/22/1990
125	AUGMENTIN	Tablets	875 mg	Dr. Reddy's Laboratories Inc.	10/02/1996
126	AUGMENTINES-600	Powder for Oral Suspension	600 mg/42.9 mg per 5 mL	Dr. Reddy's Laboratories Inc.	06/22/2001
127	AVALIDE	Tablets	150 mg/12.5 mg	Sanofi-Aventis LLC	09/01/2011 - 08/31/2012, 09/2019
128	AVALIDE	Tablets	300 mg/12.5 mg	Sanofi-Aventis LLC	09/01/2011 - 08/31/2012, 09/2019
129	AVAPRO	Tablets	75 mg	Sanofi-Aventis LLC	09/01/2011 - 08/31/2012, 09/2019
130	AVAPRO	Tablets	150 mg	Sanofi-Aventis LLC	09/01/2011 - 08/31/2012, 09/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
131	AVAPRO	Tablets	300 mg	Sanofi-Aventis LLC	09/01/2011 - 08/31/2012, 09/2019
132	AVELOX	Tablets	400 mg	Bayer HealthCare LLC	01/2014
133	AVITA	Cream	0.025%	Mylan Pharmaceuticals, Inc., a Viatris Company	05/01/1998
134	AXERT	Tablets	6.25 mg	Janssen Research & Development, LLC	07/2015
135	AXERT	Tablets	12.5 mg	Janssen Research & Development, LLC	07/2015
136	AZILECT	Tablets	1 mg	Teva Pharmaceuticals USA	01/2017
137	AZILECT	Tablets	0.5 mg	Teva Pharmaceuticals USA	01/2017
138	AZULFIDINE	Tablets	500 mg	Pharmacia and Upjohn LLC	07/14/2003
139	AZULFIDINE EN- TABS	Delayed-release Tablets	500 mg	Pharmacia and Upjohn LLC	06/17/2003
140	BENICAR HCT	Tablets	40 mg/25 mg	Daiichi Sankyo, Inc	10/2016
141	BENICAR HCT	Tablets	40 mg/12.5 mg	Daiichi Sankyo, Inc	10/2016
142	BENICAR HCT	Tablets	20 mg/12.5 mg	Daiichi Sankyo, Inc	10/2016

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	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
143	BENZACLIN	Topical Gel	1% / 5%	Bausch Health US, LLC	05/2017
144	BENZAMYCIN	Topical Gel	3% Erythromycin, 5% Benzoyl Peroxide	Bausch Health US, LLC	10/2014 - 10/2015
145	BETHKIS	Inhalation Solution	300 mg/4 mL	Chiesi USA, Inc.	09/2020
146	BETOPTIC	Ophthalmic Solution	eq. 0.5% base	Alcon Laboratories, Inc.	05/08/2000
147	BIAXIN	Granules for Oral Suspension	250 mg per 5 mL when reconstituted (100 mL bottle)	AbbVie Inc.	05/2012
148	BIAXIN	Granules for Oral Suspension	125 mg per 5 mL when reconstituted (50 mL bottle)	AbbVie Inc.	05/2012
149	BiCNU	Powder for Injection	100 mg/vial	Avet Pharmaceuticals Inc.	10/2019
150	BLOCADREN	Tablets	5 mg	Merck & Co., Inc.	Prior to 1/1/1999
151	BLOCADREN	Tablets	10 mg	Merck & Co., Inc.	Prior to 1/1/1999
152	BREVIBLOC	Injection	10 mg/mL	Baxter Healthcare Corporation	11/2002 - 10/2003
153	BRISDELLE	Capsules	7.5 mg	Sebela Ireland Limited	10/2017
154	BUMEX	Tablets	0.5 mg	Validus Pharmaceuticals LLC	10/2015

	Proprietary Name	<b>Dosage Form</b>	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
155	BUMEX	Tablets	1 mg	Validus Pharmaceuticals LLC	10/2015
156	BUMEX	Tablets	2 mg	Validus Pharmaceuticals LLC	10/2015
157	BUTRANS	Transdermal System	7.5 mcg/hour	Purdue Pharma L.P.	07/2017
158	BUTRANS	Transdermal System	5 mcg/hour	Purdue Pharma L.P.	07/2017
159	BUTRANS	Transdermal System	10 mcg/hour	Purdue Pharma L.P.	07/2017
160	BUTRANS	Transdermal System	15 mcg/hour	Purdue Pharma L.P.	07/2017
161	BUTRANS	Transdermal System	20 mcg/hour	Purdue Pharma L.P.	07/2017
162	CADUET	Tablet	5 mg/80 mg	Pharmacia & Upjohn Company LLC	04/04/2014
163	CADUET	Tablet	10 mg/20 mg	Pharmacia & Upjohn Company LLC	04/04/2014
164	CADUET	Tablet	2.5 mg/10 mg	Pharmacia & Upjohn Company LLC	04/04/2014
165	CADUET	Tablet	5 mg/40 mg	Pharmacia & Upjohn Company LLC	04/04/2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
166	CADUET	Tablet	5 mg/20 mg	Pharmacia & Upjohn Company LLC	04/04/2014
167	CADUET	Tablet	10 mg/80 mg	Pharmacia & Upjohn Company LLC	04/04/2014
168	CADUET	Tablet	10 mg/10 mg	Pharmacia & Upjohn Company LLC	04/04/2014
169	CADUET	Tablet	2.5 mg/20 mg	Pharmacia & Upjohn Company LLC	04/04/2014
170	CADUET	Tablet	2.5 mg/40 mg	Pharmacia & Upjohn Company LLC	04/04/2014
171	CADUET	Tablet	5 mg/10 mg	Pharmacia & Upjohn Company LLC	04/04/2014
172	CADUET	Tablet	10 mg/40 mg	Pharmacia & Upjohn Company LLC	04/04/2014
173	CANASA	Suppository	1000 mg	Allergan Sales, LLC	12/2018
174	CARAC	Cream	0.5%	Bausch Health US, LLC	08/2020
175	CARAFATE	Oral Suspension	1 g/10 mL	Allergan Sales, LLC	12/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
176	CARAFATE	Tablets	1 g	Allergan Sales, LLC	11/01/1996
177	CARBATROL	Extended- Release Capsules	300 mg	Takeda Pharmaceuticals U.S.A., Inc.	12/15/2011
178	CARBATROL	Extended- Release Capsules	200 mg	Takeda Pharmaceuticals U.S.A., Inc.	12/15/2011
179	CARBATROL	Extended- Release Capsules	100 mg	Takeda Pharmaceuticals U.S.A., Inc.	12/15/2011
180	CARDIOLITE	Injection	(per label)	Lantheus Medical Imaging, Inc.	12/1990
181	CARDIZEM	Tablets	30 mg	Bausch Health US, LLC	Prior to 1/1/1999
182	CARDIZEM	Tablets	60 mg	Bausch Health US, LLC	Prior to 1/1/1999
183	CARDIZEM	Tablets	90 mg	Bausch Health US, LLC	Prior to 1/1/1999
184	CARDIZEM	Tablets	120 mg	Bausch Health US, LLC	Prior to 1/1/1999
185	CARDIZEMCD	Capsules	360 mg	Bausch Health US, LLC	08/09/2012
186	CARDIZEMLA	Tablets	300 mg	Bausch Health US, LLC	02/06/2014
187	CARDIZEMLA	Tablets	420 mg	Bausch Health US, LLC	02/06/2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
188	CARDIZEMLA	Tablets	360 mg	Bausch Health US, LLC	02/06/2014
189	CARDIZEMLA	Tablets	180 mg	Bausch Health US, LLC	02/06/2014
190	CARDIZEMLA	Tablets	240 mg	Bausch Health US, LLC	02/06/2014
191	CARDURA	Tablets	8 mg	Viatris Specialty LLC	07/2014, 10/2021
192	CARDURA	Tablets	4 mg	Viatris Specialty LLC	07/2014
193	CARDURA	Tablets	2 mg	Viatris Specialty LLC	07/2014, 10/2021
194	CARDURA	Tablets	1 mg	Viatris Specialty LLC	07/2014, 11/2021
195	CARNITOR	Oral Solution	1 g/10 mL	Leadiant Biosciences, Inc.	04/2005 - 04/2006
196	CARNITOR	Tablets	330 mg	Leadiant Biosciences, Inc.	1/2005 - 12/2005
197	CASODEX	Tablets	50 mg	ANI Pharmaceuticals, Inc.	10/2020
198	CEDAX	Capsules	400 mg	Pernix Therapeutics LLC	10/22/2013
199	CEDAX	Powder, for Oral Suspension	60 mL when reconstituted (180 mg per 5 mL)	Pernix Therapeutics LLC	10/22/2013
200	CELEBREX	Capsules	400 mg	Upjohn US 2 LLC	12/10/2014
201	CELEBREX	Capsules	200 mg	Upjohn US 2 LLC	12/10/2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
202	CELEBREX	Capsules	100 mg	Upjohn US 2 LLC	12/10/2014
203	CELEBREX	Capsules	50 mg	Upjohn US 2 LLC	12/10/2014
204	CELESTONE SOLUSPAN	Injection	30 mg/5 mL (6 mg/mL)	Organon LLC, a subsidiary of Organon & Co.	02/2019
205	CHILDREN'S MOTRIN	Suspension	100 mg/5 mL	McNeil Consumer Healthcare	06/1998 - 06/1999
206	CHILDREN'S MOTRIN (aka INFANTS MOTRIN)	Suspension/ Drops	40 mg/mL	McNeil Consumer Healthcare	Prior to 1/1/1999
207	CILOXAN	Ophthalmic Solution	0.3%	Novartis Pharmaceuticals Corporation	05/28/2004
208	CIPRO	for Oral Suspension	250 mg/5 mL	Bayer Pharmaceuticals Corp.	06/2003
209	CIPRO	for Oral Suspension	500 mg/5 mL	Bayer Pharmaceuticals Corp.	06/2003
210	CIPRODEX	Otic Suspension	0.3% & 0.1%	Novartis Pharmaceuticals Corporation	08/2020
211	CLEOCIN	Vaginal Cream	2%	Pharmacia and Upjohn LLC	12/17/2005
212	CLEOCINHCI	Capsules	150 mg	Pharmacia and Upjohn LLC	07/11/2003
213	CLEOCINHCI	Capsules	300 mg	Pharmacia and Upjohn LLC	06/18/2003

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
214	CLEOCIN PHOSPHATE	Injection	600 mg/4 mL	Pharmacia and Upjohn LLC	06/2019
215	CLEOCIN PHOSPHATE	Injection	900 mg/6 mL	Pharmacia and Upjohn LLC	06/2019
216	CLEOCIN PHOSPHATE	Injection	300 mg/2 mL	Pharmacia and Upjohn LLC	06/2019
217	CLEOCIN PHOSPHATE	Injection	9,000/60 mL	Pharmacia and Upjohn LLC	06/2019
218	CLEOCINT	Topical Gel	1%	Pharmacia and Upjohn LLC	06/11/2003
219	CLEOCINT	Topical Lotion	1%	Pharmacia and Upjohn LLC	06/18/2003
220	CLIMARA	Transdermal System	0.025 mg/day	Bayer HealthCare Pharmaceuticals, Inc.	08/2018
221	CLIMARA	Transdermal System	0.375 mg/day	Bayer HealthCare Pharmaceuticals, Inc.	08/2018
222	CLIMARA	Transdermal System	0.075 mg/day	Bayer HealthCare Pharmaceuticals, Inc.	08/2018
223	CLIMARA	Transdermal System	0.05 mg/day	Bayer HealthCare Pharmaceuticals, Inc.	08/2018
224	CLIMARA	Transdermal System	0.06 mg/day	Bayer HealthCare Pharmaceuticals, Inc.	08/2018

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
225	CLIMARA	Transdermal System	1 mg/day	Bayer HealthCare Pharmaceuticals, Inc.	08/2018
226	CLINDAGEL	Gel	1%	Bausch Health U.S., LLC	06/2018
227	CLINORIL	Tablets	150 mg	Merck & Co., Inc.	Prior to 1/1/1999
228	CLINORIL	Tablets	200 mg	Merck & Co., Inc.	Prior to 1/1/1999
229	CLOBEX	Shampoo	0.05%	Galderma Laboratories, LP	01/2020
230	CLOBEX	Spray	0.05%	Galderma Laboratories, L.P.	08/2015
231	CLODERM	Cream	0.1%	EPI Health, LLC	02/17/2014
232	CLODERM	Cream	0.1%	EPI Health, LLC	09/2019
233	CLOLAR	Injection	20mg/20mL	Genzyme Corporation	05/2017
234	CLOMID	Tablets	50 mg	Hoechst Marion Roussel, Inc.	Prior to 1/1/1999
235	CLOZARIL	Tablets	50 mg	Heritage Life Sciences (USA), Inc.	03/2019
236	CLOZARIL	Tablets	200 mg	Heritage Life Sciences (USA),	05/2020

100 mg

Tablets

CLOZARIL

237

Inc.

Inc.

Heritage Life

Sciences (USA),

03/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
238	CLOZARIL	Tablets	25 mg	Heritage Life Sciences (USA), Inc.	03/2019
239	COLCRYS	Tablets	0.6 mg	Takeda Pharmaceuticals U.S.A. Inc.	07/01/2018
240	COLESTID	Granules for Oral Suspension	5 g per dose	Pharmacia and Upjohn LLC	01/11/2016
241	COLESTID	Tablets	1 g	Pharmacia and Upjohn LLC	02/2007
242	COLY-MYCINM	for Injection	150 mg/vial (single dose vial)	Par Sterile Products, LLC	06/01/2012
243	COMTAN	Tablets	200 mg	Orion Corporation	06/04/2014
244	COMTAN	Tablets	200 mg	Orion Corporation	6/26/2013
245	COMTAN	Tablets	200 mg	Orion Corporation	10/1/2012
246	CONCERTA	Extended- release Tablets	54 mg	Janssen Research and Development, LLC	02/2019
247	CONCERTA	Extended- release Tablets	18 mg	Janssen Research and Development, LLC	02/2019
248	CONCERTA	Extended- release Tablets	36 mg	Janssen Research and Development, LLC	02/2019
249	CONCERTA	Extended- release Tablets	27 mg	Janssen Research and Development, LLC	02/2019

	Proprietary Name	<b>Dosage Form</b>	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
250	CONDYLOX	Topical Solution	0.5%	Teva Branded Pharmaceuticals Products R&D, Inc	12/16/2003
251	CONZIP	Extended- release Capsules	100 mg	Cipher Pharmaceuticals, Inc.	06/2015
252	CONZIP	Extended- release Capsules	300 mg	Cipher Pharmaceuticals, Inc.	06/2015
253	CONZIP	Extended- release Capsules	200 mg	Cipher Pharmaceuticals, Inc.	05/2015
254	CORDRAN	Cream	0.05%	Almirall, LLC	04/2016
255	COREGCR	Capsules	20 mg	SmithKline Beecham (Cork) Ltd, Ireland	11/2017
256	COREGCR	Capsules	80 mg	SmithKline Beecham (Cork) Ltd, Ireland	11/2017
257	COREGCR	Capsules	10 mg	SmithKline Beecham (Cork) Ltd, Ireland	11/2017
258	COREGCR	Capsules	40 mg	SmithKline Beecham (Cork) Ltd, Ireland	11/2017
259	CORGARD	Tablets	80 mg	US WorldMeds, LLC	05/05/2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
260	CORGARD	Tablets	20 mg	US WorldMeds, LLC	05/05/2014
261	CORGARD	Tablets	40 mg	US WorldMeds, LLC	05/05/2014
262	CORTEF	Tablets	20 mg	Pharmacia and Upjohn Company LLC	12/22/2012
263	CORTEF	Tablets	10 mg	Pharmacia and Upjohn Company LLC	12/21/2012
264	CORTEF	Tablets	5 mg	Pharmacia and Upjohn Company LLC	12/21/2012
265	CORTENEMA	Rectal Suspension	100 mg/60 mL	ANI Pharmaceuticals, Inc.	08/2012
266	CORTISPORINOTIC	Otic Solution	eq. 3.5 mg base/g; 10,000 units/g; 1%	Monarch Pharmaceuticals Inc.	1/11/1999
267	COSMEGEN	Powder, for injection solution, lyophilized	500 mcg (0.5 mg)	Recordati Rare Diseases Inc.	12/2017
268	CUBICIN	Injection, powder, lyophilized, for solution	500 mg per vial	Cubist Pharmaceuticals, LLC	06/2016
269	CUPRIMINE	Capsules	250 mg	Bausch Health Americas, Inc.	12/1970

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
270	CUTIVATE	Cream	0.05%	GlaxoSmithKline Consumer Healthcare	11/2003 - 11/2004
271	CUTIVATE	Ointment	0.005%	GlaxoSmithKline Consumer Healthcare	11/2003 - 11/2004
272	CYCLESSA	Tablets	0.1 mg, 0.125 mg, 0.15 mg; 0.025 mg, 0.025 mg, 0.025 mg	Organon USA Inc.	9/15/2004
273	CYTOMEL	Tablets	50 mcg	King Pharmaceuticals R&D LLC	06/2019
274	CYTOMEL	Tablets	25 mcg	King Pharmaceuticals R&D LLC	06/2019
275	CYTOMEL	Tablets	5 mcg	King Pharmaceuticals R&D LLC	02/2019
276	CYTOTEC	Tablets	200 mcg	Pfizer Inc.	06/18/2003
277	CYTOTEC	Tablets	100 mcg	Pfizer Inc.	06/18/2003
278	DANTRIUM	Capsules	100 mg	Par Sterile Products, LLC	02/2016
279	DANTRIUM	Capsules	50 mg	Par Sterile Products, LLC	04/08/2013
280	DANTRIUM	Capsules	25 mg	Par Sterile Products, LLC	04/08/2013

	Proprietary Name	<b>Dosage Form</b>	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
281	DARAPRIM	Tablets	25 mg	Vyera Pharmaceuticals, LLC	03/2020
282	DAYPRO	Caplets	600 mg	Pfizer Inc.	03/28/2013
283	DDAVP	Nasal Solution	0.1 mL (10 mcg) per actuation	Ferring Pharmaceuticals, Inc.	07/2016
284	DDAVP	Tablets	0.1 mg	Ferring Pharmaceuticals, Inc.	12/2015
285	DDAVP	Tablets	0.2 mg	Ferring Pharmaceuticals, Inc.	12/2015
286	DDAVP, DESMOPRESSIN ACETATE	Injection	4 mcg/mL	Ferring Pharmaceuticals Inc.	01/2016
287	DELESTROGEN	Injection	40 mg/mL	Par Sterile Products	06/01/2012
288	DELESTROGEN	Injection	10 mg/mL	Par Sterile Products	06/01/2012
289	DELESTROGEN	Injection	20 mg/mL	Par Sterile Products	06/01/2012
290	DEMSER	Capsules	250 mg	Bausch Health US, LLC	09/2020
291	DEPAKOTE ER	Extended- release Tablets	500 mg	Abbvie Inc.	08/2013
292	DEPAKOTE ER	Extended- release Tablets	250 mg	Abbvie Inc.	08/2013

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
293	DEPAKOTE SPRINKLE CAPSULES	Capsules	125 mg	AbbVie Inc.	08/31/2015
294	DEPO-MEDROL	Injection	40 mg/mL	Pharmacia and Upjohn	05/2006 - 05/2007
295	DEPO-MEDROL	Injection	80 mg/mL	Pharmacia and Upjohn	05/2006 - 05/2007
296	DEPO-PROVERA	Injection	150 mg in 1 mL	Pharmacia and Upjohn LLC	09/16/2004
297	DERMA-SMOOTHE/FS (Body Oil)	Oil	0.01%	Hill Dermaceuticals Inc.	08/2013
298	DERMA-SMOOTHE/FS (Scalp Oil)	Oil	0.01%	Hill Dermaceuticals Inc.	08/2013
299	DERMOTIC	Oil	0.01%	Hill Dermaceuticals Inc.	08/2013
300	DERMOTICOIL	Oil	0.01%	Hill Dermaceuticals Inc.	08/20/2013
301	DESMOPRESSIN ACETATE	Nasal Spray	10 mcg per 0.1 mL (5 mL bottle)	Ferring Pharmaceuticals, Inc.	11/20/2014
302	DESOWEN	Cream	0.05%	Galderma Laboratories, L.P.	07/2013
303	DETROL	Tablets	2 mg	Upjohn US 2 LLC	01/2014, 01/2016
304	DETROL	Tablets	1 mg	Upjohn US 2 LLC	01/2014
305	DETROL LA	Extended- release Capsules	4 mg	Pharmacia and Upjohn LLC	12/2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
306	DETROL LA	Extended- release Capsules	2 mg	Pharmacia and Upjohn LLC	01/2016
307	DEXEDRINE SPANSULE	Extended- release Capsules	10 mg	Impax Laboratories, LLC	08/1976
308	DEXEDRINE SPANSULE	Extended- release Capsules	15 mg	Impax Laboratories, LLC	08/1976
309	DEXEDRINE SPANSULE	Extended- release Capsules	5 mg	Impax Laboratories, LLC	08/1976
310	DEXILANT	Delayed-release Capsules	30 mg	Takeda Pharmaceuticals U.S.A., Inc.	01/2022
311	DEXILANT	Delayed-release Capsules	60 mg	Takeda Pharmaceuticals U.S.A., Inc.	01/2022
312	DIABETA	Tablets	1.25 mg	Sanofi-Aventis U.S., LLC	05/01/1984
313	DIABETA	Tablets	2.5 mg	Sanofi-Aventis U.S., LLC	05/01/1984
314	DIABETA	Tablets	5 mg	Sanofi-Aventis U.S., LLC	05/01/1984
315	DIAMOX SEQUELS	Extended- release Capsules	500 mg	Teva Branded Pharmaceutical Products R&D, Inc.	12/2008

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
316	DIASTAT ACUDIAL	Gel	2.5 mg	Bausch Health US, LLC	07/1997
317	DIASTAT ACUDIAL	Gel	10 mg	Bausch Health US, LLC	07/1997
318	DIASTAT ACUDIAL	Gel	20 mg	Bausch Health US, LLC	07/1997
319	DIBENZYLINE	Capsules	10 mg	Concordia Pharmaceuticals Inc.	08/11/2015
320	DICLEGIS	Delayed-release Tablets	10 mg/10 mg	Duchesnay Inc.	11/2018
321	DIFFERIN CREAM 0.1%	Cream	0.1%	Galderma Laboratories, L.P.	10/2010
322	DIFFERINGEL 0.1%	Gel	0.1%	Galderma Laboratories, L.P.	08/23/2010
323	DIFFERINGEL 0.3%	Gel	0.3%	Galderma Laboratories, L.P.	01/2014
324	DIFLUCAN	Powder for Oral Suspension	10 mg/mL when reconstituted	Pfizer Inc.	03/12/2004
325	DIFLUCAN	Powder for Oral Suspension	40 mg/mL when reconstituted	Pfizer Inc.	03/12/2004
326	DIFLUCAN	Tablets	100 mg	Pfizer Inc.	03/12/2004
327	DIFLUCAN	Tablets	150 mg	Pfizer Inc.	03/12/2004
328	DIFLUCAN	Tablets	200 mg	Pfizer Inc.	03/12/2004
329	DILANTIN	Tablet (INFATABS)	50 mg	Parke-Davis Division of Pfizer Inc.	12/27/2012

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
330	DILANTIN-125	Oral Suspension	125 mg/5 mL (237 mL bottle)	Upjohn US 1 LLC	6/13/2012
331	DILAUDID	Solution	5 mg/5 mL (1 mg/mL)	Rhodes Pharmaceuticals L.P.	10/1/2012
332	DILAUDID	Tablets	8 mg	Rhodes Pharmaceuticals L.P.	11/23/2009
333	DILAUDID	Tablets	2 mg	Rhodes Pharmaceuticals L.P.	11/23/2009
334	DILAUDID	Tablets	4 mg	Rhodes Pharmaceuticals L.P.	11/23/2009
335	DIPROLENE	Ointment	0.05%	Merck Sharp & Dohme Corporation	8/10/2012
336	DITROPAN XL	Extended- release Tablets	5 mg	Janssen Research and Development, LLC	11/12/2015
337	DITROPAN XL	Extended- release Tablets	10 mg	Janssen Research and Development, LLC	11/12/2015
338	DIURIL	Injection	500 mg/vial, sterile lyophilized	Oak Pharmaceuticals Inc.	08/13/2012
339	DORAL	Tablets	15 mg	Galt Pharmaceuticals, LLC	8/8/13

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
340	DORIBAX	Powder for Injection	500 mg/vial	Shionogi Inc.	12/2016
341	DORIBAX	Powder for Injection	250 mg/vial	Shionogi Inc.	12/2016
342	DORYX	Delayed- Release Tablets	75 mg	Mayne Pharma International Pty Ltd.	07/08/2013
343	DORYX	Delayed- Release Tablets	50 mg	Mayne Pharma International Pty Ltd.	05/2016
344	DORYX	Delayed- Release Tablets	150 mg	Mayne Pharma International Pty Ltd.	07/08/2013
345	DORYX	Delayed- Release Tablets	100 mg	Mayne Pharma International Pty Ltd.	07/08/2013
346	DORYX	Delayed- Release Tablets	200 mg	Mayne Pharma International Pty Ltd.	02/2016
347	DORYX	Delayed- Release Tablets	80 mg	Mayne Pharma International Pty Ltd.	07/08/2013
348	DOSTINEX	Tablets	0.5 mg	Pfizer Inc.	09/22/2014
349	DOVONEX	Cream	0.005%	LEO Pharma Inc.	2012
350	DOVONEX	Ointment	0.005%	LEO Pharma Inc.	07/01/2013
351	DOXIL	Injection (Liposomal formulation)	20 mg/10 mL single use vial	Janssen Research & Development, LLC	07/2017

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
352	DOXIL	Injection (Liposomal formulation)	50 mg/25 mL single use vial	Janssen Research & Development, LLC	07/2017
353	DOXORUBICIN	Injection	150 mg/75 mL	Pharmacia and Upjohn	4/1/2013
354	DOXORUBICIN	Injection	200 mg/100 mL	Pharmacia and Upjohn	4/1/2013
355	DOXORUBICIN	Injection	50 mg/25 mL	Pharmacia and Upjohn	4/1/2013
356	DOXORUBICIN	Injection	10 mg/5 mL	Pharmacia and Upjohn	03/17/2014
357	DOXORUBICIN	Injection	20 mg/10mL	Pharmacia and Upjohn	03/17/2014
358	DOXORUBICIN	Injection	20 mg/10 mL	Pharmacia and Upjohn	4/1/2013
359	DOXORUBICIN	Injection	50 mg/25 mL	Pharmacia and Upjohn	03/17/2014
360	DOXORUBICIN	Injection	200 mg/ 100 mL	Pharmacia and Upjohn	03/17/2014
361	DOXORUBICIN	Injection	10 mg/5 mL	Pharmacia and Upjohn	4/1/2013
362	DRISDOL	Capsules	1.25 mg (50,000 IU)	Sanofi Aventis US LLC	11/10/2009
363	DUETACT	Tablets	30 mg / 4 mg	Takeda Pharmaceuticals U.S.A., Inc.	08/04/2015

	Proprietary Name	<b>Dosage Form</b>	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
364	DUETACT	Tablets	30 mg / 2 mg	Takeda Pharmaceuticals U.S.A., Inc.	08/04/2015
365	DYMISTA	Nasal Spray	137 mcg/50 mcg per spray	Mylan Specialty, L.P.	04/2020
366	DYRENIUM	Capsules	50 mg	Concordia Pharmaceuticals Inc.	08/2019
367	DYRENIUM	Capsules	100 mg	Concordia Pharmaceuticals Inc.	08/2019
368	E.E.S. GRANULES	Suspension	200 mg per 5 mL when reconstituted	Arbor Pharmaceuticals LLC	09/2016
369	EDECRIN	Powder, for Injection Solution, Lyophilized	50 mg/vial	Bausch Health Americas, Inc.	01/1967
370	EDECRIN	Tablets	25 mg	Bausch Health Americas, Inc.	01/2016 - 01/2017
371	ELDEPRYL	Capsules	5 mg	Somerset Pharmaceuticals, Inc.	05/1998 - 05/1999
372	ELDEPRYL	Tablets	5 mg	Somerset Pharmaceuticals,	06/1999 - 06/2000

1%

Cream

ELIDEL

373

Inc.

LLC

Bausch Health US, 12/2018

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
374	ELIMITE	Cream	5%	Mylan Pharmaceuticals, Inc.	06/2017
375	ELOXATIN	Injection	100 mg / 20 mL (5 mg/mL)	Sanofi-Aventis US LLC	07/07/2014
376	ELOXATIN	Injection	50 mg / 10 mL (5 mg/mL)	Sanofi-Aventis US LLC	07/07/2014
377	ELOXATIN (PREMIERPro)	Injection	50 mg/10 mL (5 mg/mL)	Sanofi-Aventis US LLC	10/2015
378	ELOXATIN (PREMIERPro)	Injection	100 mg / 20 mL (5 mg/mL)	Sanofi-Aventis US LLC	10/2015
379	EMLA	Cream	2.5% and 2.5%	Teva Branded Pharmaceutical Products R&D, Inc.	11/12/2012
380	ENTOCORTEC	Capsules	3 mg	Paddock Laboratories, LLC	08/18/2011
381	EPCLUSA	Tablets	400 mg / 100 mg	Gilead Sciences, Inc.	10/2018
382	EPIDUO	Topical Gel	0.1% / 2.5%	Galderma Laboratories, L.P.	08/2017
383	EPIPEN	Injection	0.3 mg/0.3 mL	Mylan Specialty L.P., a Viatris Company	12/15/2016
384	EPIPEN JR.	Injection	0.15/0.3 mL	Mylan Specialty L.P., a Viatris Company	12/15/2016

	Proprietary Name	<b>Dosage Form</b>	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
385	EPIVIR-HBV	Tablets	100 mg	GlaxoSmithKline LLC	09/05/2014
386	EPZICOM	Tablets	600 mg and 300 mg	ViiV Healthcare Company	09/2016
387	ERYC	Delayed- Release Capsules	250 mg	Mayne Pharma International Pty Ltd	07/29/2013
388	ERYGEL	Topical Gel	2%	Mylan Pharmaceuticals, Inc.	10/2018
389	ERYPED400	Suspension	400 mg per 5 mL when reconstituted	Arbor Pharmaceuticals LLC	03/2019
390	EVOXAC	Capsules	30 mg	Daiichi Sankyo, Inc.	03/2016
391	EXALGO	Extended- release Tablets	12 mg	SpecGx LLC	06/12/2014
392	EXALGO	Extended- release Tablets	8 mg	SpecGx LLC	06/12/2014
393	EXALGO	Extended- release Tablets	16 mg	SpecGx LLC	06/12/2014
394	EXALGO	Extended- release Tablets	32 mg	SpecGx LLC	06/12/2014
395	EXELDERM	Cream	1.0%	Journey Medical Corporation	02/2020
396	EXELDERM	Solution	1.0%	Journey Medical Corporation	02/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
397	EXTINA	Aerosol Foam	2%	Mylan Pharmaceuticals Inc.	12/2018
398	FAMVIR	Tablets	125 mg	Novartis	03/22/2011
399	FAMVIR	Tablets	250 mg	Novartis	03/22/2011
400	FAMVIR FAMVIR	Tablets	500 mg	Novartis	03/22/2011
401	FELBATOL	Oral Suspension	600 mg/5 mL	Mylan Specialty, L.P., a Viatris Company	1/2012
402	FELBATOL	Tablets	400 mg	Mylan Specialty, L.P., a Viatris Company	11/2011
403	FELBATOL	Tablets	600 mg	Mylan Specialty, L.P., a Viatris Company	11/2011
404	FELDENE	Capsules	20 mg	Pfizer Inc.	03/03/2014
105	FELDENE	Capsules	10 mg	Pfizer Inc.	03/03/2014
406	FEMCON Fe	Chewable Tablets	0.4 mg/35 mcg	Allergan Pharmaceuticals International Ltd.	10/2011
407	FENOGLIDE	Tablets	120 mg	Salix Pharmaceuticals, Inc.	03/2021
408	FENOGLIDE	Tablets	40 mg	Salix Pharmaceuticals, Inc.	06/24/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
409	FENOGLIDE	Tablets	40 mg	Salix Pharmaceuticals, Inc.	03/2021
410	FENOGLIDE	Tablets	120 mg	Salix Pharmaceuticals, Inc.	06/24/2015
411	FENTORA	Tablet	400 mcg	Cephalon, Inc.	06/2019
412	FENTORA	Tablet	600 mcg	Cephalon, Inc.	06/2019
413	FENTORA	Tablet	100 mg	Cephalon, Inc.	06/2019
414	FIBRICOR	Tablets	105 mg	Athena Biosciences, LLC	09/22/2010
415	FIBRICOR	Tablets	35 mg	Athena Biosciences, LLC	09/22/2010
416	FINACEA	Gel	15%	LEO Pharma Inc.	10/2018
417	FIORICET with CODEINE	Capsules	50 mg / 325 mg / 40 mg / 30 mg	Teva Branded Pharmaceutical Products R&D, Inc.	10/01/2003
418	FIORINAL	Capsules	50 mg / 325 mg / 40 mg	Allergan Sales, LLC	10/6/2003
419	FIORINAL with CODEINE	Capsules	50 mg / 325 mg / 40 mg / 30 mg	Allergan Sales, LLC	10/26/2006
420	FIRAZYR	Injection	30 mg / 3.0ML	Shire Human Genetic Therapies, Inc.	07/2019
421	FLECTOR	Topical System	1.3%	Institut Biochimique SA (IBSA)	03/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
422	FLECTOR	Topical System	1.3%	Institut Biochimique SA (IBSA)	03/2019
423	FLORONE	Cream	0.05%	Pharmacia and Upjohn Company	Prior to 1/1/1999
424	FLUMADINE	Tablets	100 mg	Forest Laboratories, Inc.	09/2002 - 09/2003
425	FLUOXETINE	Tablets	60 mg	Alvogen Group Holdings 3, LLC	09/2017
426	FML	Ophthalmic Suspension	0.1%	Allergan, Inc.	10/1997
427	FOCALIN XR	Extended- release Capsules	40 mg	Novartis Pharmaceuticals Corporation	03/2014
428	FOCALIN XR	Extended- release Capsules	10 mg	Novartis Pharmaceuticals Corporation	02/2015
429	FOCALIN XR	Extended- release Capsules	30 mg	Novartis Pharmaceuticals Corporation	01/2014
430	FOCALIN XR	Extended- release Capsules	15 mg	Novartis Pharmaceuticals Corporation	01/2014
431	FOCALIN XR	Extended- release Capsules	5 mg	Novartis Pharmaceuticals Corporation	11/2014
432	FORFIVO XL	Extended- release Tablets	450 mg	Alvogen Group Holdings 3, LLC	08/2018

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
433	FORFIVO XL	Extended- release Tablets	450 mg	Alvogen Group Holdings 3, LLC	09/2018
434	FORTESA	Gel	10 mg testosterone/actuation	Endo Pharmaceuticals, Inc.	08/25/2014
435	FURADANTIN	Oral Suspension	25 mg / 5 mL	Casper Pharma LLC	12/2011 - 12/2012
436	GABITRIL	Tablets	2 mg	Cephalon, Inc	12/26/2012
437	GABITRIL	Tablets	4 mg	Cephalon Inc.	12/26/2012
438	GABITRIL	Tablets	16 mg	Cephalon, Inc.	12/2012
439	GABITRIL	Tablets	12 mg	Cephalon, Inc.	12/2012
440	GASTROCROM	Oral Concentrate	100 mg/5 mL (ampule)	Mylan Specialty, L.P.	06/2015
441	GENERESS FE	Chewable Tablets	0.8 mg/25 mcg	Allergan Pharmaceuticals International Ltd.	03/2015
442	GEODON	Capsules	80 mg	Upjohn US 1 LLC	12/15/2011
443	GEODON	Capsules	20 mg	Upjohn US 1 LLC	12/15/2011
444	GEODON	Capsules	40 mg	Upjohn US 1 LLC	12/15/2011
445	GEODON	Capsules	60 mg	Upjohn US 1 LLC	12/15/2011
446	GLUCOTROL XL	Extended- release Tablets	2.5 mg	Pfizer Inc.	03/11/2004
447	GLUCOTROL XL	Extended- release Tablets	5 mg	Pfizer Inc.	03/11/2004
448	GLUCOTROL XL	Extended- release Tablets	10 mg	Pfizer Inc.	03/11/2004

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
449	GLUMETZA	Extended- release Tablets	1000 mg	Bausch Health US, LLC	06/2008
450	GLUMETZA	Extended- release Tablets	500 mg	Bausch Health US, LLC	06/2008
451	GOLYTELY	Powder for Oral Solution	PEG-3350 17.6 mmol/L, sodium 125 mmol/L, sulfate 40 mmol/L, chloride 35 mmol/L, bicarbonate 20 mmol/L and potassium 10 mmol/L (per 4 liter jug w/water)	Braintree Laboratories, Inc.	07/2009
452	GOPRELTO	Solution	4%	Genus Lifesciences Inc.	06/2018
453	GRIS-PEG	Tablets	125 mg	Bausch Health US, LLC	12/03/2012
454	GRIS-PEG	Tablets	250 mg	Bausch Health US, LLC	12/03/2012
455	HALCION	Tablets	0.125 mg	Pfizer Inc.	7/11/2003
456	HALCION	Tablets	0.25 mg	Pfizer Inc.	6/17/2003
457	HALDOL	Injection	5 mg/mL	Janssen Research & Development, LLC	7/2011
458	HALDOL DECANOATE	Injection	100 mg/mL	Janssen Research & Development, LLC	07/2011
459	HALDOL DECANOATE	Injection	50 mg/mL	Janssen Research & Development, LLC	08/2011
460	HARVONI	Tablets	90 mg and 400 mg		01/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
461	HECTOROL	Capsules, liquid filled	1 mcg	Genzyme Corporation	03/11/2014
462	HECTOROL	Capsules, liquid filled	2.5 mcg	Genzyme Corporation	03/11/2014
463	HECTOROL	Capsules, liquid filled	0.5 mcg	Genzyme Corporation	03/11/2014
464	IMITREX	Injection	6 mg/0.5 mL	GlaxoSmithKline Intellectual Prop. Ltd. England	06/2020
465	IMITREX	Injection	4 mg/0.5 mL	GlaxoSmithKline Intellectual Prop. Ltd. England	06/2020
466	IMITREX	Nasal Spray	5 mg	GlaxoSmithKline Intellectual Property Ltd. England	03/2020
467	IMITREX	Nasal Spray	20 mg	GlaxoSmithKline Intellectual Property Ltd. England	03/2020
468	IMITREX (refill)	Injection	6 mg/0.5 mL	GlaxoSmithKline Intellectual Prop. Ltd. England	06/2020
469	IMITREX (refill)	Injection	4 mg/0.5 mL	GlaxoSmithKline Intellectual Prop. Ltd. England	06/2020
470	INDERAL LA	Extended- release Capsules	120 mg	ANI Pharmaceuticals, Inc.	12/2017

	Proprietary Name	<b>Dosage Form</b>	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
471	INDERAL LA	Extended- release Capsules	60 mg	ANI Pharmaceuticals, Inc.	12/2017
472	INDERAL LA	Extended- release Capsules	160 mg	ANI Pharmaceuticals, Inc.	12/2017
473	INDERAL LA	Extended- release Capsules	80 mg	ANI Pharmaceuticals, Inc.	12/2017
474	INDERAL LA	Extended- release Capsules	60 mg	ANI Pharmaceuticals, Inc.	2/25/2009
475	INDERAL LA	Extended- release Capsules	80 mg	ANI Pharmaceuticals, Inc.	2/25/2009
476	INDERAL LA	Extended- release Capsules	120 mg	ANI Pharmaceuticals, Inc.	2/25/2009
477	INDERAL LA	Extended- release Capsules	160 mg	ANI Pharmaceuticals, Inc.	2/25/2009
478	INSPRA	Tablets	25 mg	Upjohn US 2 LLC	09/13/2007
479	INSPRA	Tablets	50 mg	Upjohn US 2 LLC	09/13/2007
480	INVANZ	Injection, Powder, Lyophylized, for Solution	1 g	Merck Sharp & Dohme Corp.	07/2018

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
481	INVEGA	Extended- release Tablets	3 mg	Janssen Research & Development, LLC	09/24/2015
482	INVEGA	Extended- release Tablets	1.5 mg	Janssen Research & Development, LLC	09/24/2015
483	INVEGA	Extended- release Tablets	6 mg	Janssen Research & Development, LLC	09/24/2015
484	INVEGA	Extended- release Tablets	9 mg	Janssen Research & Development, LLC	09/24/2015
485	IOPIDINE	Ophthalmic Solution	0.5%	Novartis Pharmaceuticals Corporation	08/2009
486	ISOPTO CARPINE	Ophthalmic Solution	1%	Novartis Pharmaceuticals Corporation	02/21/1996
487	ISOPTO CARPINE	Ophthalmic Solution	4%	Novartis Pharmaceuticals Corporation	02/21/1996
488	ISOPTO CARPINE	Ophthalmic Solution	2%	Novartis Pharmaceuticals Corporation	02/21/1996
489	ISORDIL TITRADOSE	Tablets	40 mg	Bausch Health US, LLC	03/2020
490	ISORDIL TITRADOSE	Tablets	5 mg	Bausch Health US, LLC	03/2020
491	ISTALOL	Solution	0.5%	Bausch & Lomb Incorporated	05/2018
492	ISUPREL	Injection	0.2 mg/mL	Bausch Health US, LLC	11/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
493	KADIAN	Extended- release Capsules	30 mg	Allergan Sales, LLC	11/11/2011
494	KADIAN	Extended- release Capsules	10 mg	Allergan Sales, LLC	11/11/2011
495	KADIAN	Extended- release Capsules	20 mg	Allergan Sales, LLC	11/11/2011
496	KADIAN	Extended- release Capsules	50 mg	Allergan Sales, LLC	11/11/2011
197	KADIAN	Extended- release Capsules	60 mg	Allergan Sales, LLC	11/11/2011
498	KADIAN	Extended- release Capsules	80 mg	Allergan Sales, LLC	11/11/2011
199	KADIAN	Extended- release Capsules	100 mg	Allergan Sales, LLC	11/11/2011
500	KAZANO	Tablets	12.5 mg/500 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
501	KAZANO	Tablets	12.5 mg/1000 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
502	K-DUR 10	Extended- release Tablets	10 mEq	Schering Corporation	06/2002 - 06/2003

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
503	K-DUR 20	Extended- release Tablets	20 mEq	Schering Corporation	06/1998 - 06/1999
504	KEFLEX	Capsules	750 mg	Pragma Pharmaceuticals, LLC	06/2017
505	KITABIS PAK	Inhalation Solution	300 mg/5 mL ampules	PulmoFlow Inc.	07/2016
506	KLARON	Lotion	10%	Bausch Health US, LLC	12/2005 - 12/2006
507	K-TAB	Extended- release Tablets	10 mEq (750 mg)	AbbVie Inc.	02/2011
508	K-TAB	Extended- release Tablets	20 mEq (1500 mg)	AbbVie Inc.	01/2014
509	K-TAB	Extended- release Tablets	8 mEq (600 mg)	AbbVie Inc.	02/2011
510	LAC-HYDRIN	Cream	eq. 12% base	Bristol-Myers Squibb Company	07/2004 - 06/2005
511	LAC-HYDRIN	Lotion	eq. 12% base	Bristol-Myers Squibb Company	03/2004 - 02/2005
512	LESCOL XL	Extended- release Tablets	80 mg	Novartis Pharmaceuticals Corporation	05/2018
513	LEVO-T	Tablets	100 mcg	CEDIPROF, Inc.	03/2002
514	LEVO-T	Tablets	25 mcg	CEDIPROF, Inc.	03/2002
515	LEVO-T	Tablets	50 mcg	CEDIPROF, Inc.	03/2002
516	LEVO-T	Tablets	150 mcg	CEDIPROF, Inc.	03/2002
517	LEVO-T	Tablets	75 mcg	CEDIPROF, Inc.	03/2002

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
518	LEVO-T	Tablets	88 mcg	CEDIPROF, Inc.	03/2002
519	LEVO-T	Tablets	112 mcg	CEDIPROF, Inc.	03/2002
520	LEVO-T	Tablets	125 mcg	CEDIPROF, Inc.	03/2002
521	LEVO-T	Tablets	175 mcg	CEDIPROF, Inc.	03/2002
522	LEVO-T	Tablets	300 mcg	CEDIPROF, Inc.	03/2002
523	LEVO-T	Tablets	200 mcg	CEDIPROF, Inc.	03/2002
524	LEVO-T	Tablets	150 mg	CEDIPROF, Inc.	08/2020
525	LEVO-T	Tablets	25 mg	CEDIPROF, Inc.	08/2020
526	LEVO-T	Tablets	88 mg	CEDIPROF, Inc.	08/2020
527	LEVO-T	Tablets	75 mg	CEDIPROF, Inc.	08/2020
528	LEVO-T	Tablets	100 mg	CEDIPROF, Inc.	08/2020
529	LEVO-T	Tablets	112 mg	CEDIPROF, Inc.	08/2020
530	LEVO-T	Tablets	137 mg	CEDIPROF, Inc.	08/2020
531	LEVO-T	Tablets	175 mg	CEDIPROF, Inc.	08/2020
532	LEVO-T	Tablets	137 mcg	CEDIPROF, Inc.	03/2002
533	LEVO-T	Tablets	200 mg	CEDIPROF, Inc.	08/2020
534	LEVO-T	Tablets	300 mg	CEDIPROF, Inc.	08/2020
535	LEVO-T	Tablets	50 mg	CEDIPROF, Inc.	08/2020
536	LEVO-T	Tablets	125 mg	CEDIPROF, Inc.	08/2020
537	LEXETTE	Foam	0.05%	Mayne Pharma LLC	02/2019
538	LIALDA	Delayed Release Tablets	1.2 g	Shire Development LLC	08/2017
539	LIBRAX	Capsules	5 mg/2.5 mg	Bausch Health US, LLC	09/2016 - 08/2017

	Proprietary Name	<b>Dosage Form</b>	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
540	LIDEX	Topical Solution	0.05%	County Line Pharmaceuticals, LLC	03/2018
541	LIDODERM	Patch	700 mg (50 mg per gram adhesive) in an aqueous base	Teikoku Pharma USA, Inc.	05/2014
542	LIMBITROL	Tablets	5 mg; eq. 12.5 mg base	Valeant Pharmaceuticals International	01/2006 - 12/2006
543	LIMBITROL DS	Tablets	10 mg; eq. 25 mg base	Valeant Pharmaceuticals International	01/2007 - 12/2007
544	LIORESAL	Injection	0.5 mg/mL	Medtronic Inc	06/1999 - 05/2000
545	LIORESAL	Injection	2 mg/mL	Medtronic Inc	06/1999 - 05/2000
546	LIPITOR	Tablets	10 mg	Upjohn Manufacturing Ireland Unlimited	1/28/2013
547	LIPITOR	Tablets	80 mg	Upjohn Manufacturing Ireland Unlimited	1/28/2013
548	LIPITOR	Tablets	20 mg	Upjohn Manufacturing Ireland Unlimited	1/28/2013
549	LIPITOR	Tablets	40 mg	Upjohn Manufacturing Ireland Unlimited	1/28/2013
550	LIPOFEN	Capsules	150 mg	Cipher Pharmaceuticals, Inc.	04/2016

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
551	LIPOFEN	Capsules	50 mg	Cipher Pharmaceuticals, Inc.	04/2016
552	LITHOBID	Extended- release Tablets	300 mg	ANI Pharmaceuticals, Inc.	12/2016
553	LOCOID	Cream	0.1%	Bausch Health U.S., LLC	07/2013
554	LOCOID	Lotion	0.1%	Bausch Health US, LLC	06/2018
555	LOCOID (Ointment)	Ointment	0.1%	Bausch Health US, LLC	10/2015 - 10/2016
556	LOCOID (Solution)	Topical Solution	0.1%	Bausch Health US, LLC	02/1987
557	LOCOID LIPOCREAM	Cream	0.1%	Bausch Health US, LLC	07/03/2013
558	LODOSYN	Tablets	25 mg	Bausch Health Americas, Inc.	04/2014
559	LOESTRIN 24 Fe Fe	Tablets	1 mg/20 mcg	Allergan Pharmaceuticals International Ltd.	11/05/2015
560	LOMOTIL	Tablet	2.5 mg/0.025 mg	Pfizer Inc.	07/2011, 02/2013
561	LOPID	Tablets	600 mg	Pfizer Pharmaceuticals Ltd.	11/2020
562	LOPRESSOR HCT	Tablets	1 mg/mL	Novartis Pharmaceuticals Corporation	03/1998 - 03/1999

	Proprietary Name	<b>Dosage Form</b>	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
563	LOPRESSOR HCT	Tablets	50mg/25mg	Novartis Pharmaceuticals Corporation	11/25/2009
564	LOPRESSOR HCT	Tablets	100 mg / 25 mg	Novartis Pharmaceuticals Corporation	11/25/2009
565	LOPROX	Cream	0.77%	Medicis Pharmaceutical Corporation	12/2004 - 11/2005
566	LOPROX	Gel	0.77%	Alvogen, Inc.	07/2007 - 06/2008
567	LOPROX	Shampoo	1%	Medicis Pharmaceutical Corporation	12/2012
568	LOPROX	Topical Suspension	0.77%	Medimetriks Pharmaceuticals, Inc.	12/2003 - 11/2004
569	LoSEASONIQUE	Tablets	0.1 mg/0.02 mg and 0.01 mg	Teva Branded Pharmaceutical Products R&D, Inc.	12/07/2010
570	LoSEASONIQUE	Tablets	0.1 mg/0.02 mg and 0.01 mg	Teva Branded Pharmaceutical Products R&D, Inc.	11/10/2016
571	LOTEMAX	Ophthalmic Suspension	0.5%	Bausch & Lomb Incorporated	07/2019
572	LOTENSIN HCT	Tablets	20 mg; 25 mg	Validus Pharmaceuticals LLC	04/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
573	LOTENSIN HCT	Tablets	20 mg; 12.5 mg	Validus Pharmaceuticals LLC	04/2019
574	LOTENSINHCT	Tablets	10 mg; 12.5 mg	Validus Pharmaceuticals LLC	04/2019
575	LOTORNEX	Tablets	0.5 mg	Sebela Ireland Limited	05/2015
576	LOTRIMIN AF	Cream	1%	Schering-Plough HealthCare Products, Inc	03/1998 - 03/1999
577	LOTRONEX	Tablets	1 mg	Sebela Ireland Limited	05/2015
578	LOTRONEX	Tablets	0.5 mg	Sebela Ireland Limited	05/2015
579	LOVENOX	Injection	120 mg/0.8 mL graduated prefilled syringe	Sanofi Aventis US LLC	05/2015
580	LOVENOX	Injection	150 mg/1 mL graduated prefilled syringe	Sanofi Aventis US LLC	05/2015
581	LOVENOX	Injection	40 mg/0.4 mL prefilled syringe	Sanofi Aventis US LLC	10/2011
582	LOVENOX	Injection	60 mg/0.6 mL graduated prefilled syringe	Sanofi Aventis US LLC	10/2011
583	LOVENOX	Injection	80 mg/0.8 mL graduated prefilled syringe	Sanofi Aventis US LLC	10/2011
584	LOVENOX	Injection	30 mg/0.3 mL prefilled syringe	Sanofi Aventis US LLC	03/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
585	LOVENOX	Injection	60 mg/0.6 mL graduated prefilled syringe	Sanofi Aventis US LLC	03/2015
586	LOVENOX	Injection	30 mg/0.3 mL prefilled syringe	Sanofi Aventis US LLC	10/2011
587	LOVENOX	Injection	80 mg/0.8 mL graduated prefilled syringe	Sanofi Aventis US, LLC	03/2015
588	LOVENOX	Injection	100 mg/1 mL graduated prefilled syringe	Sanofi Aventis US LLC	03/2015
589	LOVENOX	Injection	300 mg/3 mL multi-dose vial	Sanofi Aventis US LLC	03/2015
590	LOVENOX	Injection	100 mg/1 mL graduated prefilled syringe	Sanofi Aventis US LLC	10/2011
591	LOVENOX	Injection	300 mg/3 mL multi-dose vial	Sanofi Aventis US LLC	10/2011
592	LOVENOX	Injection	150 mg/1 mL graduated prefilled syringe	Sanofi Aventis US LLC	10/2011
593	LOVENOX	Injection	120 mg/0.8 mL graduated prefilled syringe	Sanofi Aventis US LLC	10/2011
594	LOVENOX	Injection	40 mg/0.4 mL prefilled syringe	Sanofi Aventis US, LLC	03/2015
595	LOZOL	Tablets	2.5 mg	Rhone-Poulenc Rorer Pharmaceuticals Inc.	Prior to 1/1/1999
596	LUVOX	Tablets	25 mg	ANI Pharmaceuticals, Inc.	08/09/2011

	Proprietary Name	<b>Dosage Form</b>	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
597	LUVOX	Tablets	50 mg	ANI Pharmaceuticals, Inc.	08/09/2011
598	LUVOX	Tablets	100 mg	ANI Pharmaceuticals, Inc.	08/09/2011
599	LUXIQ	Foam	0.12%	Mylan Pharmaceuticals, Inc.	04/2017
600	LUZU	Cream	1%	Bausch Health US, LLC	07/2018
601	LYRICA	Capsules	150 mg	Upjohn US 2 LLC	07/2019
602	LYRICA	Capsules	300 mg	Upjohn US 2 LLC	07/2019
603	LYRICA	Capsules	225 mg	Upjohn US 2 LLC	07/2019
604	LYRICA	Capsules	50 mg	Upjohn US 2 LLC	07/2019
605	LYRICA	Capsules	25 mg	Upjohn US 2 LLC	07/2019
606	LYRICA	Capsules	200 mg	Upjohn US 2 LLC	07/2019
607	LYRICA	Capsules	75 mg	Upjohn US 2 LLC	07/2019
608	LYRICA	Capsules	100 mg	Upjohn US 2 LLC	07/2019
609	LYRICA	Oral Solution	20 mg per mL	Upjohn US 2 LLC	07/2019
610	LYSTEDA	Tablets	650 mg	Amring Pharmaceuticals Inc.	03/17/2016
611	MACROBID	Capsules	100 mg	Almatica Pharma LLC	02/2011
612	MACRODANTIN	Capsules	100 mg	Almatica Pharma LLC	08/2011

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
613	MACRODANTIN	Capsules	50 mg	Almatica Pharma LLC	08/2011
614	MACRODANTIN	Capsules	25 mg	Alvogen PB Research and Development, LLC	09/2010
615	MALARONE	Tablets	250 mg/100 mg	GlaxoSmithKline LLC	7/31/2012
616	MARINOL	Capsules	2.5 mg	AbbVie Inc.	05/2017
617	MARINOL	Capsules	10 mg	AbbVie Inc.	05/2017
618	MARINOL	Capsules	5 mg	AbbVie Inc.	05/2017
619	MAXITROL	Ophthalmic Ointment	3.5 mg and 10000 units and 0.1% / gram	Novartis Pharmaceuticals Corporation	03/04/1996
620	MAXZIDE	Tablets	75 mg and 50 mg	Mylan Pharmaceuticals Inc.	Prior to 1/1/1999
621	MAXZIDE-25	Tablets	37.5 mg and 25 mg	Mylan Pharmaceuticals Inc.	Prior to 1/1/1999
622	MEDROL	Tablets	32 mg	Pfizer Inc.	4/22/2013
623	MEDROL	Tablets	4 mg	Pfizer Inc.	11/16/2011
624	MEDROL	Tablets	16 mg	Pfizer Inc.	4/22/2013
625	MEDROL	Tablets	8 mg	Pfizer Inc.	4/22/2013
626	MEGACE ES	Oral Suspension	625 mg/5 mL (125 mg/mL)	Endo Pharmaceuticals, Inc.	07/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
627	MEPHYTON	Tablets	5 mg	Bausch Health Americas, Inc.	04/2018
628	MESNEX	Injection	100 mg/mL	Baxter Healthcare Corporation	12/2003 - 12/2004
629	MESTINON	Oral Solution	60 mg / 5 mL	Bausch Health US, LLC	07/2019
630	MESTINON	Tablets	60 mg	Bausch Health US, LLC	04/2002 - 03/2003
631	MESTINON TIMESPAN	Tablets	180 mg	Bausch Health US, LLC	11/2015
632	METADATE CD	Extended- release Capsules	20 mg	Lannett Company, Inc.	09/2012
633	METADATE CD	Extended- release Capsules	60 mg	Lannett Company, Inc.	09/2012
634	METADATE CD	Extended- release Capsules	40 mg	Lannett Company, Inc.	09/2012
635	METADATE CD	Extended- release Capsules	30 mg	Lannett Company, Inc.	09/2012
636	METADATE CD	Extended- release Capsules	10 mg	Lannett Company, Inc.	09/2012
637	METADATE CD	Extended- release Capsules	50 mg	Lannett Company, Inc.	09/2012

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
538	METHYLIN	Oral Solution	10 mg/5 mL	Mallinckrodt Inc.	08/01/2013
539	METHYLIN	Oral Solution	5 mg/5 mL	Mallinckrodt Inc.	08/01/2013
640	METROCREAM	Cream	0.75%	Galderma Laboratories, L.P.	3/2009
641	METROGEL	Gel	1%	Galderma Laboratories, L.P.	02/2017
642	METROGEL	Gel	0.75%	Galderma Laboratories, L.P.	03/2014
643	METROGEL VAGINAL GEL	Vaginal Gel	0.75%	Bausch Health US, LLC	04/01/2015
644	METROLOTION	Lotion	0.75%	Galderma Laboratories, L.P.	6/16/2009
645	MIACALCIN	Nasal Spray	200 I.U. per actuation	Sebela Ireland Ltd.	12/09/2008
646	MICARDIS	Tablets	40 mg	Boehringer Ingelheim Pharmaceuticals, Inc.	11/13/2013
647	MICARDIS HCT	Tablets	80 mg/25 mg	Boehringer Ingelheim Pharmaceuticals, Inc.	02/28/2014
648	MICARDIS HCT	Tablets	80 mg/12.5 mg	Boehringer Ingelheim Pharmaceuticals, Inc.	02/28/2014
649	MICARDIS HCT	Tablets	40 mg/12.5 mg	Boehringer	02/28/2014

Ingelheim

	Proprietary Name	<b>Dosage Form</b>	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
				Pharmaceuticals, Inc.	
650	MICRO-K EXTENCAPS	Extended- Release Capsules	10 mEq (750 mg)	Nesher Pharmaceuticals USA LLC	01/19/2011
651	MICRO-K EXTENCAPS	Extended- Release Capsules	8 mEq (600 mg)	Nesher Pharmaceuticals USA LLC	03/10/2011
652	MICRONASE	Tablets	2.5 mg	Pharmacia and Upjohn	Prior to 1/1/1999
653	MICRONASE	Tablets	5 mg	Pharmacia and Upjohn	Prior to 1/1/1999
654	MICROZIDE	Capsules	12.5 mg	Teva Branded Pharmaceutical Products R&D, Inc.	10/05/2001
655	MIDAMOR	Tablets	5 mg	Paddock Laboratories	04/06/2009
656	MIGRANAL	Nasal Spray	4 mg in 1 mL	Bausch Health US, LLC	03/18/2013
657	MINASTRIN 24 FE	Tablets	1 mg/20 mcg	Allergan Pharmaceuticals International Limited	03/2017
658	MINIPRESS	Capsules	1 mg	Pfizer Inc.	01/2017
659	MINIPRESS	Capsules	5 mg	Pfizer Inc.	01/2017
660	MINIPRESS	Capsules	2 mg	Pfizer Inc.	01/2017

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
661	MINIVELLE	Film, Extended Release	0.1 mg per day	Noven Pharmaceuticals, Inc.	01/2018
662	MINIVELLE	Film, Extended Release	0.025 mg per day	Noven Pharmaceuticals, Inc.	01/2018
663	MINIVELLE	Film, Extended Release	0.0375 mg per day	Noven Pharmaceuticals, Inc.	01/2018
664	MINIVELLE	Film, Extended Release	0.075 mg per day	Noven Pharmaceuticals, Inc.	01/2018
665	MINIVELLE	Film, Extended Release	0.05 mg per day	Noven Pharmaceuticals, Inc.	01/2018
666	MITIGARE	Capsules	0.6 mg	Hikma International Pharmaceuticals LLC	10/01/2014
667	MOBIC	Oral Suspension	7.5 mg/5 mL	Boehringer Ingelheim Pharmaceuticals Inc.	6/12/2006
668	MONODOX	Capsules	75 mg	Aqua Pharmaceuticals LLC	10/2014
669	MONODOX	Capsules	50 mg	Aqua Pharmaceuticals LLC	02/07/2005

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
670	MONODOX	Capsules	100 mg	Aqua Pharmaceuticals LLC	02/07/2005
671	MONOKET	Tablets	10 mg	Kremers Urban Pharmaceuticals, Inc.	06/30/1996 - 06/29/1997
672	MONOKET	Tablets	20 mg	Kremers Urban Pharmaceuticals, Inc.	06/30/1996 - 06/29/1997
673	MOVIPREP	Powder for Oral Solution	100 g/7.5 g/2.691 g/1.015 g/5.9 g/4.7 g	Salix Pharmaceuticals, Inc.	09/2020
674	MOXATAG	Extended- Release Tablets	775 mg	Vernalis (R&D) Limited	08/20/2014
675	MSCONTIN	Extended- release Tablets	15 mg	Purdue Pharma L.P.	05/2005 - 05/2006
676	MSCONTIN	Extended- release Tablets	30 mg	Purdue Pharma L.P.	05/2005 - 05/2006
677	MSCONTIN	Extended- release Tablets	60 mg	Purdue Pharma L.P.	05/2005 - 05/2006
678	MS CONTIN	Extended- release Tablets	100 mg	Purdue Pharma L.P.	05/2005 - 05/2006
679	MS CONTIN	Extended- release Tablets	200 mg	Purdue Pharma L.P.	05/2005 - 05/2006
680	MUCINEX	Extended- release Tablets	600 mg	RB Health (US), LLC	02/2018
681	MUCINEX	Extended- release Tablets	600 mg	RB Health (US), LLC	02/2018

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
682	MUCINEX	Extended- release Tablets	600 mg	RB Health (US), LLC	02/2018
583	MUCINEX	Extended- release Tablets	600 mg	RB Health (US) LLC	02/2018
584	MUCINEX	Extended- release Tablets	600 mg	RB Health (US), LLC	02/2018
585	MUCINEX	Extended- release Tablets	600 mg	RB Health (US), LLC	02/2018
686	MUCINEX (MAXIMUM STRENGTH)	Extended- release Tablets	1200 mg	RB Health (US), LLC	12/2017
87	MUCINEX (MAXIMUM STRENGTH)	Extended- release Tablets	1200 mg	RB Health (US), LLC	10/2017
588	MUCINEX (MAXIMUM STRENGTH)	Extended- release Tablets	1200 mg	RB Health (US) LLC	08/2017
589	MUCINEX (MAXIMUM STRENGTH)	Extended- release Tablets	1200 mg	RB Health (US), LLC	08/2017
590	MUCINEX (MAXIMUM STRENGTH)	Extended- release Tablets	1200 mg	RB Health (US), LLC	08/2017
591	MUCINEX (MAXIMUM STRENGTH)	Extended- release Tablets	1200 mg	RB Health (US), LLC	02/2018
92	MUCINEX (MAXIMUM STRENGTH)	Extended- release Tablets	1200 mg	RB Health (US), LLC	08/2017
593	MUCINEX DM	Extended- release Tablets	1200 mg and 60 mg	RB Health (US) LLC	09/2017

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
694	MUCINEX DM	Extended- release Tablets	600 mg and 30 mg	RB Health (US) LLC	10/2019
695	MUCINEX DM	Extended- release Tablets	600 mg and 30 mg	RB Health (US) LLC	05/2019
696	MUCINEX DM	Extended- release Tablets	1200 mg and 60 mg	RB Health (US) LLC	09/2017
697	MUCINEX DM	Extended- release Tablets	1200 mg and 60 mg	RB Health (US) LLC	10/2017
698	MYAMBUTOL	Tablets	100 mg	STI Pharma LLC	12/15/2006
699	MYAMBUTOL	Tablets	400 mg	STI Pharma LLC	12/15/2006
700	MYCOBUTIN	Capsules	150 mg	Pharmacia and Upjohn LLC	05/13/2014
701	MYSOLINE	Tablets	250 mg	Bausch Health US, LLC	05/2018
702	MYSOLINE	Tablets	50 mg	Bausch Health US, LLC	05/2018
703	NALFON	Capsules	200 mg	Xspire Pharma LLC	04/2017
704	NALFON	Capsules	400 mg	Xspire Pharma LLC	05/2016
705	NALFON	Capsules	400 mg	Xspire Pharma LLC	08/05/2015
706	NAMENDA	Tablets	5 mg and 10 mg (titration pak)	Allergan Sales, LLC	04/01/2015
707	NAMENDA	Tablets	5 mg	Allergan Sales, LLC	04/01/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
708	NAMENDA	Tablets	10 mg	Allergan Sales, LLC	04/01/2015
709	NAMENDA XR	Capsules	7 mg	Allergan Sales, LLC	05/2019
710	NAMENDA XR	Capsules	14 mg	Allergan Sales, LLC	05/2019
711	NAMENDA XR	Capsules	28 mg	Allergan Sales, LLC	05/2019
712	NAMENDA XR	Capsules	21 mg	Allergan Sales, LLC	05/2019
713	NAPRELAN	Controlled- Release Tablets	750 mg	Almatica Pharma LLC	03/2015
714	NAPRELAN	Controlled- Release Tablets	375 mg	Almatica Pharma LLC	09/2015
715	NAPRELAN	Controlled- Release Tablets	500 mg	Almatica Pharma LLC	03/2015
716	NAPROSYN	Suspension	125 mg/5 mL	Atnahs Pharma US Limited	11/2016
717	NAPROSYN EC (EC- NAPROSYN)	Delayed- Release Tablets	375 mg	Atnahs Pharma US Limited	10/2018
718	NAPROSYN EC (EC- NAPROSYN)	Delayed- Release Tablets	500 mg	Atnahs Pharma US Limited	10/2018
719	NARDIL	Tablet	15 mg	Parke-Davis	3/23/2011
720	NASACORT AQ	Nasal Spray Spray Bottle	55 mcg/spray	Sanofi Aventis US, LLC	06/15/2011
721	NATROBA	Topical Suspension	0.9%	ParaPRO LLC	06/2014

	Proprietary Name	<b>Dosage Form</b>	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
722	NEOPROFEN	Injection	20mg/2mL (10mg/mL)	Recordati Rare Diseases Inc.	04/2016
723	NESINA	Tablets	12.5 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
724	NESINA	Tablets	6.25 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
725	NESINA	Tablets	25 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
726	NEURONTIN	Capsules	100 mg	Upjohn US 1 LLC	3/17/2004
727	NEURONTIN	Capsules	300 mg	Upjohn US 1 LLC	03/17/2004
728	NEURONTIN	Capsules	400 mg	Upjohn US 1 LLC	3/17/2004
729	NEURONTIN	Oral Solution	250 mg per 5 mL	Upjohn US 1 LLC	3/24/2011
730	NEURONTIN	Tablets	600 mg	Upjohn US 1 LLC	3/17/2004
731	NEURONTIN	Tablets	800 mg	Upjohn US 1 LLC	3/17/2004
732	NIASPAN	Extended- release Tablets	1000 mg	AbbVie Inc.	06/30/2014
733	NIASPAN	Extended- release Tablets	750 mg	AbbVie Inc.	06/30/2014
734	NIASPAN	Extended- release Tablets	500 mg	AbbVie Inc.	06/30/2014
735	NICORETTE	Chewing Gum	2 mg	GlaxoSmithKline Consumer Healthcare L.P.	01/2002 - 01/2003

	Proprietary Name	<b>Dosage Form</b>	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
736	NICORETTE	Chewing Gum	4 mg	GlaxoSmithKline Consumer Healthcare L.P.	06/2001 - 06/2002
737	NILANDRON	Tablets	150 mg	Concordia Pharmaceuticals Inc.	11/2019
738	NITRO-DUR	Transdermal	0.6 mg/hr	USpharma Ltd.	04/2020
739	NITRO-DUR	Transdermal	0.2 mg/hr	USpharma Ltd.	04/2020
740	NITRO-DUR	Transdermal	0.1 mg/hr	USpharma Ltd.	04/2020
741	NITRO-DUR	Transdermal	0.4 mg/hr	USpharma Ltd.	04/2020
742	NITROLINGUAL PUMPSPRAY	Lingual Spray	400 mcg per Spray	G. Pohl-Boskamp GmbH & Co.	02/01/2011
743	NITROSTAT	Tablets	0.6 mg	Upjohn US 1 LLC	08/26/2016
744	NITROSTAT	Tablets	0.4 mg	Upjohn US 1 LLC	08/26/2016
745	NITROSTAT	Tablets	0.3 mg	Upjohn US 1 LLC	08/26/2016
746	NORFLEX	Extended- release Tablets	100 mg	3M Pharmaceuticals	Prior to 1/1/1999
747	NORPACE	Capsules	100 mg	Pfizer Inc.	04/2019
748	NORPACE	Capsules	150 mg	Pfizer Inc.	04/2019
749	NORPRAMIN	Tablets	10 mg	Sanofi-Aventis US LLC	04/2014
750	NORPRAMIN	Tablets	150 mg	Sanofi-Aventis US LLC	04/2014
751	NORPRAMIN	Tablets	25 mg	Sanofi-Aventis US LLC	04/2014
752	NORPRAMIN	Tablets	50 mg	Sanofi-Aventis US LLC	Prior to 1/1/1999

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
753	NORPRAMIN	Tablets	75 mg	Sanofi-Aventis US LLC	04/2014
754	NORPRAMIN	Tablets	100 mg	Sanofi-Aventis US LLC	04/2014
755	NOR-QD	Tablets	0.35 mg	Teva Branded Pharmaceuticals Products R&D, Inc	06/06/2003
756	NORVASC	Tablets	2.5 mg	Upjohn US 1 LLC	6/15/2006
757	NORVASC	Tablets	5 mg	Upjohn US 1 LLC	6/15/2006
758	NORVASC	Tablets	10 mg	Upjohn US 1 LLC	6/15/2006
759	NOXAFIL	Delayed-release Tablets	100 mg	Merck Sharp & Dohme Corp.	08/2019
760	NULYTELY	Powder (for reconstitution with water)	Per 4 liter jug: polyethylene glycol 3350 420 g, sodium bicarbonate 5.72 g, sodium chloride 11.2 g, potassium chloride 1.48 g, flavoring 2 g	Braintree Laboratories, Inc.	02/2013
761	NUMBRINO	Nasal Solution	4%	Lannett Company, Inc.	09/2020
762	NUVARING	Vaginal Ring	11.7 mg / 2.7 mg (delivers 0.120 mg/0.015 mg per day)	Organon USA Inc.	12/2019
763	NUVIGIL	Tablets	200 mg	Teva Pharmaceuticals USA	12/2016
764	NUVIGIL	Tablets	150 mg	Teva Pharmaceuticals USA	11/2016

	Proprietary Name	<b>Dosage Form</b>	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
765	NUVIGIL	Tablets	150 mg	Teva Pharmaceuticals USA	12/2016
766	NUVIGIL	Tablets	50 mg	Teva Pharmaceuticals USA	12/2016
767	NUVIGIL	Tablets	250 mg	Teva Pharmaceuticals USA	11/2016
768	NUVIGIL	Tablets	250 mg	Teva Pharmaceuticals USA	12/2016
769	NUVIGIL	Tablets	200 mg	Teva Pharmaceuticals USA	11/2016
770	NUVIGIL	Tablets	50 mg	Teva Pharmaceuticals USA	11/2016
771	OLUX	Foam	0.05%	Mylan Pharmaceuticals Inc.	12/2018
772	OLUX-E	Emulsion, Aerosol Foam	0.05%	Mylan Pharmaceuticals Inc., a Viatris Company	01/2019
773	OMNIPRED	Ophthalmic Suspension	1%	Novartis Pharmaceuticals Corporation	01/1995

	Proprietary Name	<b>Dosage Form</b>	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
774	OPTIVAR	Ophthalmic Solution	0.05%	Meda Pharmaceuticals, Inc.	03/10/2011
775	ORABLOC	Injection	4% and 1:200,000	Pierrel S.p.A.	10/2016
776	ORABLOC	Injection	4% and 1:100,000	Pierrel S.p.A.	10/2016
777	ORACEA	Capsules	40 mg	Galderma Laboratories, L.P.	04/2015
778	ORAPRED ODT	Orally Disintegrating Tablets	10 mg	Concordia Pharmaceuticals Inc.	10/2015
779	ORAPRED ODT	Orally Disintegrating Tablets	15 mg	Concordia Pharmaceuticals Inc.	10/2015
780	ORAPRED ODT	Orally Disintegrating Tablets	30 mg	Concordia Pharmaceuticals Inc.	10/2015
781	OSENI	Tablets	25 mg/15 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
782	OSENI	Tablets	25 mg/45 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
783	OSENI	Tablets	12.5 mg/30 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
784	OSENI	Tablets	25 mg/30 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
785	OTOVEL	Otic Solution	0.3% / 0.025%	Laboratorios SALVAT, S.A.	11/2019
786	OVIDE	Lotion	0.5%	Taro Pharmaceuticals USA, Inc.	08/02/2008 - 08/01/2009
787	OXANDRIN	Tablets	2.5 mg	Savient Pharmaceuticals, Inc.	06/2006 - 05/2007
788	OXANDRIN	Tablets	10 mg	Savient Pharmaceuticals, Inc.	06/2006 - 05/2007
789	OXYCODONE HYDROCHLORIDE	Oral Solution	5 mg/5 mL	Genus Lifesciences, Inc.	09/2013
790	OXYCONTIN	Extended- release Tablets	20 mg	Purdue Pharma L.P.	03/24/2015
791	OXYCONTIN	Extended- release Tablets	20 mg	Purdue Pharma L.P.	12/2020
792	OXYCONTIN	Extended- release Tablets	10 mg	Purdue Pharma L.P.	03/24/2015
793	OXYCONTIN	Extended- release Tablets	40 mg	Purdue Pharma L.P.	12/2020
794	OXYCONTIN	Extended- release Tablets	40 mg	Purdue Pharma L.P.	03/24/2015
795	OXYCONTIN	Extended- release Tablets	80 mg	Purdue Pharma L.P.	03/24/2015
796	OXYCONTIN	Extended- release Tablets	10 mg	Purdue Pharma L.P.	12/2020

	Proprietary Name	<b>Dosage Form</b>	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
797	PARAPLATIN	for Injection	50 mg/vial	Bristol-Myers Squibb Company	03/2004 - 02/2005
798	PARAPLATIN	for Injection	150 mg/vial	Bristol-Myers Squibb Company	03/2004 - 02/2005
799	PARAPLATIN	for Injection	450 mg/vial	Bristol-Myers Squibb Company	03/2004 - 02/2005
800	PARAPLATINAQ	Injection	eq. 50 mg/5 mL (10 mg/mL)	Bristol-Myers Squibb Company	07/2004 - 06/2005
801	PARAPLATINAQ	Injection	eq. 150 mg/15 mL (10 mg/mL)	Bristol-Myers Squibb Company	07/2004 - 06/2005
802	PARAPLATINAQ	Injection	eq. 450 mg/45 mL (10 mg/mL)	Bristol-Myers Squibb Company	07/2004 - 06/2005
803	PARAPLATINAQ	Injection	eq. 600 mg/60 mL (10 mg/mL)	Bristol-Myers Squibb Company	07/2004 - 06/2005
804	PARLODEL	Capsules	5 mg	Validus Pharmaceuticals LLC	12/1998, 4/2006
805	PARLODEL	Tablets	2.5 mg	Validus Pharmaceuticals LLC	Prior to 1/1/1999
806	PARNATE	Tablets	10 mg	Concordia Pharmaceuticals Inc.	02/05/2016
807	PATADAY	Ophthalmic Solution	0.2%	Alcon Laboratories	06/2017
808	PATADAY	Ophthalmic Solution	0.1%	Alcon Laboratories, Inc.	09/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
809	PATANASE	Nasal Spray	665 mcg in 100 mg solution	Novartis Pharmaceuticals Corporation	04/2015
810	PATANOL	Ophthalmic Solution	0.1%	Novartis Pharmaceuticals Corporation	09/15/2015
811	PAXIL CR	Tablets	12.5 mg	GlaxoSmithKline	10/21/2010
812	PAXIL CR	Tablets	25 mg	GlaxoSmithKline	10/21/2010
813	PAXIL CR	Tablets	37.5 mg	GlaxoSmithKline	10/21/2010
814	PEDIAPRED	Oral Solution	5 mg / 5 mL	Seton Pharmaceuticals, LLC	02/2002
815	PHOSLO	Gelcaps	667 mg	Fresenius Medical Care North America	06/2019
816	PHOSLO	Gelcaps	667 mg	Fresenius Medical Care North America	03/2014 - 03/2015
817	PLAN B ONE-STEP	Tablets	1.5 mg	Foundation Consumer Healthcare, LLC	02/12/2014
818	PLAQUENIL	Tablets	200 mg	Concordia Pharmaceuticals Inc.	05/1999 - 04/2000
819	PLENDIL	Extended- release Tablets	2.5 mg	AstraZeneca LP	10/2008
820	PLENDIL	Extended- release Tablets	5 mg	AstraZeneca LP	10/2008

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
821	PLENDIL	Extended- release Tablets	10 mg	AstraZeneca LP	10/2008
822	PLIAGLIS	Cream	7%/7%	Taro Pharmaceuticals USA, Inc.	11/2017
823	POLYTRIM	Ophthalmic Solution	10 mL unit	Allergan, Inc.	04/29/1997
824	PONSTEL	Capsules	250 mg	Shionogi, Inc.	07/11/2011
825	POTASSIUM CHLORIDEFOR ORAL SOLUTION	Powder for Solution	20 mEq	Pharma Research Software Solution, LLC	09/2015
826	POTASSIUM CHLORIDEFOR ORAL SOLUTION	Powder for Solution	20 mEq	Pharma Research Software Solution, LLC	01/2017
827	POTASSIUM CHLORIDEORAL SOLUTION, USP, 10%	Oral Solution	20 mEq per 15 mL	Lehigh Valley Technologies	05/14/2015
828	POTASSIUM CHLORIDEORAL SOLUTION, USP, 10%	Oral Solution	20 mEq per 15 mL	Lehigh Valley Technologies	05/14/2015
829	POTASSIUM CHLORIDEORAL SOLUTION, USP, 20%	Oral Solution	40 mEq per 15 mL	Lehigh Valley Technologies	05/14/2015
830	PRAVACHOL	Tablets	10 mg	Bristol-Myers Squibb Company	10/2005 - 09/2006
831	PRAVACHOL	Tablets	20 mg	Bristol-Myers Squibb Company	10/2005 - 09/2006
832	PRAVACHOL	Tablets	40 mg	Bristol-Myers Squibb Company	10/2005 - 09/2006

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
833	PRAVACHOL	Tablets	80 mg	Bristol-Myers Squibb Company	10/2005 - 09/2006
834	PREDFORTE	Ophthalmic Suspension	1%	Allergan, Inc.	08/1997
835	PREVACID	Delayed- Release Capsules	15 mg	Takeda Global Research & Development Center, Inc.	11/2009
836	PREVACID	Delayed- Release Capsules	30 mg	Takeda Global Research & Development Center, Inc.	11/2009
837	PREVPAC	Delayed- Release Capsules, Capsules, and Tablets	30 mg, 500 mg, and 500 mg	Takeda Pharmaceuticals U.S.A., Inc.	03/02/2015
838	PRISTIQ	Extended- Release Tablets	50 mg	PF Prism C.V.	03/2017
839	PRISTIQ	Extended- Release Tablets	100 mg	PF Prism C.V.	03/2017
840	PRISTIQ	Extended- Release Tablets	25 mg	PF Prism C.V.	03/2017
841	PROAIR HFA	Inhalation Aerosol	90 mcg per acutation	Teva Branded Pharmaceutical Products R&D, Inc.	01/2019
842	PROCARDIA	Capsules	10 mg	Pfizer Inc.	3/25/2013

	Proprietary Name	<b>Dosage Form</b>	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
843	PROMETRIUM	Capsules	200 mg	Virtus Pharmaceuticals, LLC	07/2016
844	PROMETRIUM	Capsules	100 mg	Virtus Pharmaceuticals, LLC	07/30/2010
845	PROMETRIUM	Capsules	100 mg	Virtus Pharmaceuticals, LLC	07/2016
846	PROMETRIUM	Capsules	200 mg	Virtus Pharmaceuticals, LLC	07/30/2010
847	PROTOPIC	Ointment	0.1%	LEO Pharma Inc.	11/2014
848	PROTOPIC	Ointment	0.03%	LEO Pharma Inc.	11/2014
849	PROVENTIL HFA	Inhalation Aerosol	90 mcg per actuation	Kindeva Drug Delivery L.P.	03/2021
850	PROVENTIL HFA	Inhalation Aerosol	90 mcg per actuation	Kindeva Drug Delivery L.P.	04/2019
851	PROVERA	Tablets	2.5 mg	Pharmacia and Upjohn	6/18/2003
852	PROVERA	Tablets	5 mg	Pharmacia and Upjohn	6/18/2003
853	PROVERA	Tablets	10 mg	Pharmacia and Upjohn	6/18/2003
854	PROVIGIL	Tablets	100 mg	Cephalon, Inc.	03/29/2012
855	PROVIGIL	Tablets	200 mg	Cephalon Inc.	03/29/2012

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
856	PURINETHOL	Tablets	50 mg	Stason Pharmaceuticals Inc.	11/2016
857	QUALAQUIN	Capsules	324 mg	Sun Pharmaceutical Industries, Inc.	07/23/2012
858	QUARTETTE	Tablets	0.15 mg/0.02 mg, 0.15 mg/0.025 mg, 0.15 mg/0.03 mg, and 0.01 mg	Teva Branded Pharmaceutical Products R&D, Inc.	04/2017
859	QUDEXY XR	Extended- release Capsules	100 mg	Upsher-Smith Laboratories, LLC	07/07/2014
860	QUDEXY XR	Extended- release Capsules	200 mg	Upsher-Smith Laboratories, LLC	07/07/2014
861	QUDEXY XR	Extended- release Capsules	25 mg	Upsher-Smith Laboratories, LLC	07/07/2014
862	QUDEXY XR	Extended- release Capsules	50 mg	Upsher-Smith Laboratories, LLC	07/07/2014
863	QUDEXY XR	Extended- release Capsules	150 mg	Upsher-Smith Laboratories, LLC	07/07/2014
864	RAPAMUNE	Oral Solution	1 mg/mL	PF Prism C.V.	07/2019
865	RAPAMUNE	Tablets	0.5 mg	PF Prism C.V.	01/16/2014
866	RAPAMUNE	Tablets	2 mg	PF Prism CV	10/27/2014

PF Prism CV

10/27/2014

867 RAPAMUNE

Tablets

1 mg

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
868	RAZADYNE	Tablets	4 mg	Janssen Research & Development, LLC	08/28/2008
869	RAZADYNE	Tablets	8 mg	Janssen Research & Development, LLC	08/28/2008
870	RAZADYNE ER	Capsules	8 mg	Janssen Research & Development, LLC	10/13/2008
871	RAZADYNE ER	Capsules	16 mg	Janssen Research & Development, LLC	10/13/2008
872	RAZADYNE ER	Capsules	24 mg	Janssen Research & Development, LLC	10/13/2008
873	REGLAN	Injection	eq. 5 mg base/mL	Baxter Healthcare Corporation	02/2003 - 02/2004
874	REGLAN	Tablets	5 mg	ANI Pharmaceuticals, Inc.	12/2021
875	REGLAN	Tablets	10 mg	ANI Pharmaceuticals, Inc.	12/2021
876	RELPAX	Tablets	40 mg	Upjohn Manufacturing Ireland Unltd	07/2017
877	RELPAX	Tablets	20 mg	Upjohn Manufacturing Ireland Unltd	07/2017
878	RENVELA	Tablets	800 mg	Genzyme Corporation	04/16/2014
879	RESTORIL	Capsules	22.5 mg	Mallinckrodt Inc.	07/21/2008
880	RESTORIL	Capsules	7.5 mg	Mallinckrodt Inc.	07/22/2008

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
881	RETIN-A	Cream	0.1 %	Bausch Health US, LLC	01/26/1973
882	RETIN-A	Cream	0.025%	Bausch Health US, LLC	09/2014 - 09/2015
883	RETIN-A	Cream	0.025%	Bausch Health US, LLC	04/2019
884	RETIN-A	Cream	0.05%	Bausch Health US, LLC	02/06/2014
885	RETIN-A	Cream	0.1%	Bausch Health US, LLC	07/2019
886	RETIN-A	Cream	0.05%	Valeant Pharmaceuticals North America, LLC	07/19/1974
887	RETIN-A	Cream	0.05%	Bausch Health US, LLC	12/2018
888	RETIN-A	Gel	0.01 %	Bausch Health US, LLC	08/2019
889	RETIN-A	Gel	0.025%	Bausch Health US, LLC	06/2005
890	RETIN-A MICRO	Gel	0.1 %	Bausch Health US, LLC	08/2019
891	RETIN-A MICRO	Gel	0.1 %	Bausch Health US, LLC	03/2013
892	RETIN-A MICRO	Gel	0.04%	Bausch Health US, LLC	03/2013

Bausch Health US, 08/2019

LLC

893 RETIN-AMICRO

Gel

0.04 %

	Proprietary Name	<b>Dosage Form</b>	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
894	REVATIO	Powder for Suspension	10 mg/mL	Upjohn 1 US LLC	09/2019
895	REVATIO	Tablets	20 mg	Upjohn 1 US LLC	11/2012, 11/2020
896	RISPERDAL	Oral Solution	1 mg/mL	Janssen Research & Development, LLC	06/30/2008
897	RITALIN	Tablet	20 mg	Novartis Pharmaceuticals Corp	Prior to 1/1/1999
898	RITALIN	Tablet	10 mg	Novartis Pharmaceuticals Corp	Prior to 1/1/1999
899	RITALIN	Tablet	5 mg	Novartis Pharmaceuticals Corp	Prior to 1/1/1999
900	RITALINLA	Capsules	30 mg	Novartis Pharmaceuticals Corp	11/2015
901	RITALINLA	Capsules	40 mg	Novartis Pharmaceuticals Corp	11/2015
902	RITALINLA	Capsules	10 mg	Novartis Pharmaceuticals Corp	02/2018
903	RITALINLA	Capsules	20 mg	Novartis Pharmaceuticals Corp	11/2015
904	ROBINUL	Injection	0.2 mg/mL	Eurohealth International Sarl	02/06/1975

	Proprietary Name	<b>Dosage Form</b>	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
905	ROBINUL	Tablets	1 mg	Shionogi Pharma, Inc.	01/13/2005
906	ROBINUL FORTE	Tablets	2 mg	Shionogi Pharma, Inc.	01/13/2005
907	ROCALTROL	Oral Solution	1 mcg/mL (15 mL bottle)	Validus Pharmaceuticals LLC	08/26/2009
908	ROGAINE (FOR MEN)	Topical Solution	2%	McNeil-PPC, Inc.	06/1998 - 05/1999
909	ROGAINE (FOR WOMEN)	Topical Solution	2%	McNeil-PPC, Inc.	06/1998 - 05/1999
910	ROGAINE EXTRA STRENGTH (FOR MEN)	Topical Solution	5%	McNeil-PPC, Inc.	2004
911	ROWASA	Rectal Suspension Enema	4 g/60 mL	Mylan Specialty, L.P., a Viatris Company	2/2011
912	SAFRYAL	Tablets	3 mg / 0.03 mg / 0.451 mg	Bayer HealthCare LLC	08/2015
913	SALAGEN	Tablets	5 mg	Concordia Pharmaceuticals Inc.	12/2004
914	SALAGEN	Tablets	7.5 mg	Concordia Pharmaceuticals Inc.	03/2006 - 01/2007
915	SAMSCA	Tablets	15 mg	Otsuka Pharmaceutical Company, Ltd.	10/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
916	SAMSCA	Tablets	30 mg	Otsuka Pharmaceutical Company, Ltd.	05/2020
917	SAPHRIS SAPHRIS	Sublingual Tablets	10 mg	Allergan Sales, LLC	12/2020
918	SEASONALE	Tablets	0.15 mg/0.03 mg	Teva Branded Pharmaceutical Products R&D, Inc.	9/7/2006
919	SEASONIQUE	Tablets	0.15 mg/0.03 mg and 0.01 mg	Teva Branded Pharmaceutical Products R&D, Inc.	07/28/2010
920	SECTRAL	Capsules	eq. 200 mg base	Wyeth Laboratories, Inc.	Prior to 1/1/1999
921	SECTRAL	Capsules	eq. 400 mg base	Wyeth Laboratories, Inc.	Prior to 1/1/1999
922	SEPTOCAINE	Injection	4% and 1:200,000	Deproco, Inc.	01/2015
923	SEPTOCAINE	Injection	4% and 1:100,000	Deproco, Inc.	01/2016
924	SEPTOCAINE	Injection	4% and 1:200,000	Deproco, Inc.	04/2019
925	SEPTOCAINE	Injection	4% and 1:100,000	Deproco, Inc.	04/2005
926	SEPTOCAINE	Injection	4% and 1:100,000	Deproco, Inc.	04/2019
927	SEPTOCAINE	Injection	4% and 1:100,000	Deproco, Inc.	01/2015
928	SEPTOCAINE	Injection	4% and 1:200,000	Deproco, Inc.	01/2015
929	SEPTOCAINE	Injection	4% and 1:200,000	Deproco, Inc.	01/2015
930	SEPTOCAINE	Injection	4% and 1:100,000	Deproco, Inc.	01/2015
931	SEPTOCAINE	Injection	4% and 1:100,000	Deproco, Inc.	01/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
932	SEROQUEL XR	Extended- release Tables	200 mg	AstraZeneca UK Limited	05/2017
933	SEROQUEL XR	Extended- release Tablets	50 mg	AstraZeneca UK Limited	11/2016
934	SEROQUEL XR	Extended- release Tablets	150 mg	AstraZeneca UK Limited	05/2017
935	SEROQUEL XR	Extended- release Tablets	50 mg	AstraZeneca UK Limited	05/2017
936	SEROQUEL XR	Extended- release Tablets	300 mg	AstraZeneca UK Limited	05/2017
937	SEROQUEL XR	Extended- release Tablets	400 mg	AstraZeneca UK Limited	05/2017
938	SEROQUEL XR	Extended- release Tablets	150 mg	AstraZeneca UK Limited	11/2016
939	SEROQUEL XR	Extended- release Tablets	200 mg	AstraZeneca UK Limited	11/2016
940	SEROQUEL XR	Extended- release Tablets	300 mg	AstraZeneca UK Limited	11/2016
941	SILENOR	Tablets	6 mg	Currax Pharmaceuticals LLC	08/2010
942	SILENOR	Tablets	3 mg	Currax Pharmaceuticals LLC	08/2010
943	SILVADENE	Cream	1%	King Pharmaceuticals LLC	01/2018

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
944	SKELAXIN	Tablets	800 mg	King Pharmaceuticals R&D, LLC	08/2018
945	SODIUM EDECRIN	Powder, for Solution	50 mg/vial (single dose vial for preparation of IV solution)	Aton Pharma, Inc.	01/2015 - 01/2016
946	SOLARAZE	Gel	3%	Fougera Pharmaceuticals, Inc.	11/21/2013
947	SOLODYN	Extended- release Tablets	105 mg	Bausch Health US, LLC	10/2018
948	SOLODYN	Extended- release Tablets	55 mg	Bausch Health US, LLC	10/2018
949	SOLODYN	Extended- release Tablets	115 mg	Bausch Health US, LLC	02/2018
950	SOLODYN	Extended- release Tablets	65 mg	Bausch Health US, LLC	02/2018
951	SOLODYN	Extended- release Tablets	80 mg	Bausch Health US, LLC	10/2018
952	SOMA	Tablet	250 mg	Mylan Specialty, L.P.	9/13/2010
953	SOOLANTRA	Cream	1%	Galderma Laboratories, L.P.	06/2021
954	SORILUX	Foam	0.005%	Mayne Pharma LLC	08/2020
955	SORILUX	Foam	0.005%	Mayne Pharma LLC	02/2021

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	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
956	SPECTRACEF	Tablets	200 mg	Vansen Pharma, Inc.	Unknown
957	SPECTRACEF	Tablets	400 mg	Vansen Pharma, Inc.	Unknown
958	SPORANOX	Capsule	100 mg	Janssen Research & Development, LLC	2/2005; 6/2005
959	SPORANOX	Oral Solution	10 mg/mL	Janssen Research & Development, LLC	10/2018
960	STALEVO 100	Film-coated Tablets	25 mg, 100 mg, 200 mg	Orion Corporation	06/2014
961	STALEVO 100	Film-coated Tablets	25 mg, 100 mg, 200 mg	Orion Corporation	10/2012
962	STALEVO 125	Film-coated Tablets	31.25 mg, 125 mg, 200 mg	Orion Corporation	4/2012
963	STALEVO 125	Film-coated Tablets	31.25 mg, 125 mg, 200 mg	Orion Corporation	06/2014
964	STALEVO 150	Film-coated Tablets	37.5mg, 150 mg, 200 mg	Orion Corporation	06/2014
965	STALEVO 150	Film-coated Tablets	37.5 mg, 150 mg, 200 mg	Orion Corporation	10/2012
966	STALEVO 200	Film-coated Tablets	50 mg, 200 mg, 200 mg	Orion Corporation	06/2014
967	STALEVO 200	Film-coated Tablets	50 mg, 200 mg, 200 mg	Orion Corporation	4/2012
968	STALEVO 50	Film-coated Tablets	12.5 mg, 50 mg, 200 mg	Orion Corporation	4/2012
969	STALEVO 50	Film-coated Tablets	12.5 mg, 50 mg, 200 mg	Orion Corporation	06/2014

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	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
970	STALEVO75	Film-coated Tablets	18.75 mg, 75 mg, 200 mg	Orion Corporation	4/2012
971	STALEVO75	Film-coated Tablets	18.75 mg, 75 mg, 200 mg	Orion Corporation	10/2013
972	STALEVO75	Film-coated Tablets	18.75 mg, 75 mg, 200 mg	Orion Corporation	06/2014
973	STELEVO 100	Film-coated Tablets	25 mg, 100 mg, 200 mg	Orion Corporation	10/2013
974	STELEVO 125	Film-coated Tablets	31.25 mg, 125 mg, 200 mg	Orion Corporation	10/2013
975	STELEVO 150	Film-coated Tablets	37.5 mg, 150 mg, 200 mg	Orion Corporation	10/2013
976	STELEVO 200	Film-coated Tablets	50 mg, 200 mg, 200 mg	Orion Corporation	10/2013
977	STELEVO 50	Film-coated Tablets	12.5 mg, 50 mg, 200 mg	Orion Corporation	02/2015
978	STRATTERA	Capsules	10 mg	Eli Lilly and Company	05/2017
979	STRATTERA	Capsules	100 mg	Eli Lilly and Company	05/2017
980	STRATTERA	Capsules	80 mg	Eli Lilly and Company	05/2017
981	STRATTERA	Capsules	60 mg	Eli Lilly and Company	05/2017
982	STRATTERA	Capsules	40 mg	Eli Lilly and Company	05/2017
983	STRATTERA	Capsules	25 mg	Eli Lilly and Company	05/2017

	Proprietary Name	<b>Dosage Form</b>	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
984	STRATTERA	Capsules	18 mg	Eli Lilly and Company	05/2017
985	SULAR	Extended- release Tablets	34 mg	Covis Pharma GmbH/Cardinal Health Regulatory	2/2012 - 2/2013
986	SULAR	Extended- release Tablets	8.5 mg	Covis Pharma GmbH/Cardinal Health Regulatory	2/2012 - 2/2013
987	SULAR	Extended- release Tablets	17 mg	Covis Pharma GmbH/Cardinal Health Regulatory	2/2012 - 2/2013
988	SUPRAX	Capsules	400 mg	Lupin Limited	10/2020
989	SYMBICORT	Metered Dose Inhaler	160/4.5 mcg	AstraZeneca Pharmaceuticals LP	01/2020
990	SYMBICORT	Metered Dose Inhaler	80/4.5 mcg	AstraZeneca Pharmaceuticals LP	01/2020
991	SYNALAR	Cream	0.01%	Medimetriks Pharmaceuticals, Inc.	12/2012
992	SYNALAR	Cream	0.025%	Medimetriks Pharmaceuticals, Inc.	12/2012
993	SYNALAR	Ointment	0.025%	Medimetriks Pharmaceuticals, Inc.	12/2012

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	<b>Proprietary Name</b>	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
994	SYNALGOS-DC	Capsules	356.4 mg/30 mg/16 mg	Sun Pharmaceutical Industries, Inc.	10/01/2012
995	SYPRINE	Capsules	250 mg	Bausch Health Americas, Inc.	02/2018
996	TACLONEX	Ointment	0.005%/0.064%	LEO Pharma A/S	01/2020
997	TACLONEX	Topical Suspension	0.005%/0.064%	LEO Pharma Inc.	01/2020
998	TAMBOCOR	Tablets	50 mg	3M Pharmaceuticals	10/2002
999	TAMBOCOR	Tablets	100 mg	3M Pharmaceuticals	10/2002
1000	TAMBOCOR	Tablets	150 mg	3M Pharmaceuticals	10/2002
1001	TARGRETIN	Capsules	75 mg	Bausch Health Ireland, Limited	12/2015
1002	TARKA	Extended- release Tablets	4 mg Trandolapril, 240 mg Verapamil Hydrochloride	AbbVie	02/25/2015
1003	TARKA	Extended- release Tablets	2 mg Trandolapril, 240 mg Verapamil Hydrochloride	AbbVie	02/25/2015
1004	TARKA	Extended- release Tablets	2 mg Trandolapril, 180 mg Verapamil Hydrochloride	AbbVie	02/25/2015
	TASMAR	Tablets	100 mg	Bausch Health US, LLC	07/2004
1006	TAXOTERE	Injection Concentrate	160 mg/8 mL (20 mg/mL)	Sanofi Aventis US LLC	10/2016
1007	TAXOTERE	Injection Concentrate	20 mg/mL	Sanofi Aventis US LLC	03/2011

	<b>Proprietary Name</b>	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
	TAXOTERE	Injection Concentrate	80 mg/4 mL (20 mg/mL)	Sanofi Aventis US LLC	03/2011
	TAYTULLA	Capsules	1 mg/20 mcg	Allergan Pharmaceuticals International Ltd	11/2020
1010	TAZORAC	Cream	0.1%	Allergan Aesthetics, an Abbvie Company	10/2016
1011	TAZORAC	Cream	0.05%	Allergan Aesthetics, an Abbvie Company	10/2016
1012	TEGRETOL XR	Tablets	100 mg	Novartis Pharmaceuticals Corporation	03/2016
1013	TEGRETOL XR	Tablets	200 mg	Novartis Pharmaceuticals Corporation	06/15/2009
1014	TEGRETOL XR	Tablets	400 mg	Novartis Pharmaceuticals Corporation	06/15/2009
1015	TESSALON	Perles	100 mg	Pfizer Inc.	01/2020
1016	TESTIM	Gel	50 mg in 5 g	Auxilium Pharmaceuticals, Inc.	06/09/2014
1017	TETRACAINE HYDROCHLORIDE	Ophthalmic Solution	0.5%	Bausch Health Ireland Limited	06/2019

	<b>Proprietary Name</b>	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
	TIAZAC	Extended- release Capsules	120 mg	Bausch Health US, LLC Bausch Health US, LLC	08/20/2014
	TIAZAC	Extended- release Capsules	420 mg	Bausch Health US, LLC	08/20/2014
1020	TIAZAC	Extended- release Capsules	360 mg	Bausch Health US, LLC	08/20/2014
1021	TIAZAC	Extended- release Capsules	180 mg	Bausch Health US, LLC	08/20/2014
1022	TIAZAC	Extended- release Capsules	240 mg	Bausch Health US, LLC	08/20/2014
1023	TIAZAC	Extended- release Capsules	300 mg	Bausch Health US, LLC Bausch Health US, LLC	08/20/2014
1024	TIGAN	Injection	100 mg/mL	Par Sterile Products, LLC	06/01/2012
	TIMOPTIC	Ophthalmic Solution	0.5%	Bausch Health America, Inc.	06/2020
1026	TIMOPTIC in OCUDOSE	Solution	0.5%	Bausch Health Americas, Inc.	04/2021
1027	TIROSINT	Capsules	13 mcg	IBSA Pharma Inc.	11/2020
	TIROSINT	Capsules	125 mcg	IBSA Pharma Inc.	11/2020
	TIROSINT	Capsules	100 mcg	IBSA Pharma Inc.	11/2020
1030	TIROSINT	Capsules	88 mcg	IBSA Pharma Inc.	11/2020

	<b>Proprietary Name</b>	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1031	TIROSINT	Capsules	75 mcg	IBSA Pharma Inc.	11/2020
1032	TIROSINT	Capsules	50 mcg	IBSA Pharma Inc.	11/2020
1033	TIROSINT	Capsules	137 mcg	IBSA Pharma Inc.	11/2020
1034	TIROSINT	Capsules	150 mcg	IBSA Pharma Inc.	11/2020
	TIROSINT	Capsules	175 mcg	IBSA Pharma Inc.	11/2020
1036	TIROSINT	Capsules	200 mcg	IBSA Pharma Inc.	11/2020
1057	TIROSINT	Capsules	112 mcg	IBSA Pharma Inc.	11/2020
	TIROSINT	Capsules	25 mcg	IBSA Pharma Inc.	11/2020
1039	TIVORBEX	Capsules	40 mg	Genus Lifesciences Inc.	01/2020
1040	TIVORBEX	Capsules	20 mg	Genus Lifesciences Inc.	01/2020
1041	TOBI	Solution for Inhalation	300 mg/5 mL ampule	Mylan Specialty, L.P., a Viatris Company	07/2014
	TOBRADEX	Opthalmic Suspension	0.3%, 0.1%	Novartis Pharmaceuticals Corporation	01/02/2009
	TOFRONIL PM	Capsules	100 mg	Mallinckrodt Inc.	4/2006
	TOFRONIL PM	Capsules	125 mg	Mallinckrodt Inc.	4/2006
	TOFRONIL PM	Capsules	150 mg	Mallinckrodt Inc.	4/2006
	TOFRONIL PM	Capsules	75 mg	Mallinckrodt Inc.	4/2006
	TOPROL XL	Extended- release Tablets	50 mg	Toprol Acquisition LLC	01/2018
1048	TOPROL XL	Extended- release Tablets	100 mg	Toprol Acquisition LLC	01/2018

	<b>Proprietary Name</b>	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
	TOPROL XL	Extended- release Tablets	200 mg	Toprol Acquisition LLC	01/2018
	TOPROL XL	Extended- release Tablets	25 mg	Toprol Acquisition LLC	01/2018
1051	TORADOL	Tablets	10 mg	Syntex (U.S.A.) Inc.	Prior to 1/1/1999
1052	TRANDATE	Tablets	100 mg	Alvogen, Inc.	12/01/2014
1053	TRANDATE	Tablets	200 mg	Alvogen, Inc.	03/2018
1054	TRANDATE	Tablets	300 mg	Alvogen, Inc.	03/2018
	TRAVATANZ	Ophthalmic Solution	0.004%	Novartis Pharmaceuticals Corporation	12/2019
1056	TREXIMET	Tablets	85 mg/500 mg	Currax Pharmaceuticals LLC	02/2018
1057	TRIBENZOR	Tablets	20 mg/5 mg/12.5 mg	Daiichi Sankyo, Inc.	10/2016
1058	TRIBENZOR	Tablets	40 mg/5 mg/12.5 mg	Daiichi Sankyo, Inc.	10/2016
1059	TRIBENZOR	Tablets	40 mg/5 mg/25 mg	Daiichi Sankyo, Inc.	10/2016
1060	TRIBENZOR	Tablets	40 mg/10 mg/12.5 mg	Daiichi Sankyo, Inc.	10/2016
1061	TRIBENZOR	Tablets	40 mg/10 mg/25 mg	Daiichi Sankyo, Inc.	10/2016
1062	TRILEPTAL	Oral Suspension	300 mg/5 mL	Novartis Pharmaceuticals Corporation	12/2009

	<b>Proprietary Name</b>	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
	TRILIPIX	Delayed Release Capsules	135 mg	AbbVie Inc.	07/15/2013
	TRILIPIX	Delayed Release Capsules	45 mg	AbbVie Inc.	07/15/2013
	TRI-NORINYL	Tablets	0.5 mg, 1 mg, 0.5 mg; 0.035 mg, 0.035 mg, 0.035 mg	Mayne Pharma LLC	1/12/2005
1066	TUSSIONEX	Extended- Release Suspension	10 mg hydrocodone bitartrate & 8 mg chlorpheniramine maleate per 5 mL	UCB, Inc.	10/2010
1067	UCERIS	Extended- Release Tablets	9 mg	Salix Pharmaceuticals Inc.	07/2018
1068	ULTRAVATE	Cream	0.05%	Bristol-Myers Squibb Company	11/2004 - 10/2005
	ULTRAVATE	Ointment	0.05%	Bristol-Myers Squibb Company	11/2004 - 10/2005
070	UNITHROID	Tablets	137 mcg (0.137 mg)	Jerome Stevens Pharmaceuticals, Inc.	unknown
1071	UNITHROID	Tablets	25 mcg (0.025 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1072	UNITHROID	Tablets	50 mcg (0.05 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003

	<b>Proprietary Name</b>	<b>Dosage Form</b>	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1073	UNITHROID	Tablets	75 mcg (0.075 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
	UNITHROID	Tablets	88 mcg (0.088 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
	UNITHROID	Tablets	100 mcg (0.1 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
	UNITHROID	Tablets	112 mcg (0.112 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1077	UNITHROID	Tablets	125 mcg (0.125 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1078	UNITHROID	Tablets	150 mcg (0.15 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1079	UNITHROID	Tablets	175 mcg (0.175 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1080	UNITHROID	Tablets	200 mcg (0.2 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1081	UNITHROID	Tablets	300 mcg (0.3 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1082	UREX	Tablets	1 gram	County Line Pharmaceuticals, LLC	05/2010
1083	UROCIT-K	Extended- release Tablets	540 mg (5 mEq per tablet)	Mission Pharmacal Company	11/2007
	UROCIT-K	Extended- release Tablets	15 mEq (1620 mg) per tablet	Mission Pharmacal Company	12/23/2013
	URSO 250	Tablets	250 mg	Allergan Sales, LLC	07/06/2009
	URSO FORTE	Tablets	500 mg	Allergan Sales, LLC	07/06/2009
	VAGISTAT-1	Vaginal Ointment	6.50%	Bristol-Myers Squibb Company	02/1998 - 02/1999
1088	VANCOCIN	Capsules	250 mg	ANI Pharmaceuticals Inc.	10/26/2015
1089	VANCOCIN	Capsules	125 mg	ANI Pharmaceuticals Inc.	10/26/2015
1090	VANOS	Cream	0.1%	Bausch Health US, LLC	01/2014
	VASERETIC	Tablets	10 mg/25 mg	Valeant Pharmaceuticals North America, LLC	10/31/1986
1092	VASOTEC	Tablets	20 mg	Bausch Health US, LLC	12/24/1985

	<b>Proprietary Name</b>	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
	VASOTEC	Tablets	2.5 mg	Bausch Health US, LLC	07/26/1988
	VASOTEC	Tablets	5 mg	Bausch Health US, LLC	12/24/1985
1095	VASOTEC	Tablets	10 mg	Bausch Health US, LLC	12/24/1985
1096	VECTICAL	Ointment	3 mcg/g	Galderma Laboratories, L.P.	02/28/2012
1097	VELTIN	Gel	1.2%/0.025%	Almirall, LLC	06/2018
1098	VENLAFAXINE HYDROCHLORIDE EXTENDED RELEASE TABLETS	Tablet, Extended Release	37.5 mg	Osmotica Pharmaceutical US LLC	04/2010
1099	VENLAFAXINE HYDROCHLORIDE EXTENDED RELEASE TABLETS	Tablet, Extended Release	225 mg	Osmotica Pharmaceutical US LLC	04/2010
1100	VENLAFAXINE HYDROCHLORIDE EXTENDED RELEASE TABLETS	Tablet, Extended Release	150 mg	Osmotica Pharmaceutical US LLC	04/2010
1101	VENLAFAXINE HYDROCHLORIDE EXTENDED RELEASE TABLETS	Tablet, Extended Release	75 mg	Osmotica Pharmaceutical US LLC	04/2010
1102	VENOFER	Injection	2% w/v iron (Fe)	Luitpold Pharmaceuticals, Inc.	10/02/08
1103	VENTOLINHFA	Metered-dose Inhaler	90 mcg per actuation	GlaxoSmithKline Intellectual Property Mgmt Ltd	01/2019

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	<b>Proprietary Name</b>	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
	VERELAN	Sustained- release Capsules	120 mg	Recro Gainesville LLC	5/17/1999
	VERELAN	Sustained- release Capsules	180 mg	Recro Gainesville LLC	5/17/1999
1106	VERELAN	Sustained- release Capsules	240 mg	Recro Gainesville LLC	5/17/1999
	VERELAN	Sustained- release Capsules	360 mg	Recro Gainesville LLC	5/17/1999
1108	VERELANPM	Extended- release Capsules	100 mg	Recro Gainesville LLC	11/2006 - 11/2007
1109	VERELANPM	Extended- release Capsules	200 mg	Recro Gainesville LLC	11/2006 - 11/2007
	VERELANPM	Extended- release Capsules	300 mg	Recro Gainesville LLC	11/2006 - 11/2007
1111	VFEND	Powder for Oral Suspension	40 mg/mL (75 mL when reconstituted)	PF Prism C.V.	12/16/2013
1112	VFEND	Tablets	50 mg	PF Prism C.V.	07/08/2010
1113	VFEND	Tablets	200 mg	PF Prism C.V.	07/08/2010
	VIAGRA	Tablets	100 mg	Upjohn US 1 LLC	12/2017
	VIAGRA	Tablets	25 mg	Upjohn US 1 LLC	12/2017
1116	VIAGRA	Tablets	50 mg	Upjohn US 1 LLC	12/2017

	<b>Proprietary Name</b>	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1117	VIBRAMYCIN	Capsules	100 mg	Pfizer Inc.	05/2015
1118	VIDAZA	Injection, Powder, Lyophylized, for Solution	100 mg single-dose vial	Celgene Corporation	09/16/2013
	VIGAMOX	Ophthalmic Solution	0.5%	Novartis Pharmaceuticals Corporation	01/2017
1120	VIMOVO	Delayed-release Tablets	375 mg/20 mg	Horizon Medicines, LLC	03/2020
1121	VIMOVO	Delayed-release Tablets	500 mg/20 mg	Horizon Medicines, LLC	03/2020
1122	VIRAMUNE	Oral Suspension	50 mg/5 mL	Boehringer- Ingleheim Pharmaceuticals, Inc.	05/21/2012
1123	VIRAMUNE	Tablets	200 mg	Boehringer- Ingleheim Pharmaceuticals, Inc.	05/21/2012
	VIRAZOLE	Powder for Solution	6g/100 mL vial, to be reconstituted	Bausch Health US, LLC	04/2017
	VOGELXO	Gel	50 mg	Upsher-Smith Laboratories, LLC	06/2014
1126	VOLTAREN	Delayed-release Tablets	25 mg	Novartis Pharmaceuticals Corporation	Prior to 1/1/1999

	<b>Proprietary Name</b>	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1127	VOLTAREN	Delayed-release Tablets	50 mg	Novartis Pharmaceuticals Corporation	Prior to 1/1/1999
	VOLTAREN	Gel	1%	GlaxoSmithKline Consumer Healthcare	07/2016
	VOLTAREN XR	Extended- release Tablets	100 mg	Novartis Pharmaceuticals Corporation	05/22/2000
	VUSION	Ointment	0.25%, 15%, and 81.35%	Mylan Pharmaceuticals Inc., a Viatris Company	11/2018
1131	WELCHOL	Oral Solution	3.75 g packet	Daiichi Sankyo Inc.	07/2018
1132	WELCHOL	Tablets	625 mg	Daiichi Sankyo, Inc.	05/2018
1133	XALATAN	Ophthalmic Solution	0.005% (125 mcg/2.5 mL)	Upjohn US 2, LLC	11/15/2010
1134	XANAX	Tablets	0.25 mg	Upjohn US 2 LLC	06/17/2003
1135	XANAX	Tablets	0.5 mg	Upjohn US 2 LLC	06/18/2003
	XANAX	Tablets	1 mg	Upjohn US 2 LLC	06/18/2003
1137	XANAX	Tablets	2 mg	Upjohn US 2 LLC	06/18/2003
	XANAX XR	Extended- release Tablets	0.5 mg	Upjohn US 2 LLC	11/16/2005
1139	XANAX XR	Extended- release Tablets	1 mg	Upjohn US 2 LLC	11/16/2005

	<b>Proprietary Name</b>	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
	XANAX XR	Extended- release Tablets	2 mg	Upjohn US 2 LLC	11/16/2005
1141	XANAX XR	Extended- release Tablets	3 mg	Upjohn US 2 LLC	11/16/2005
1142	XIMINO	Extended- release Capsules	45 mg	Journey Medical Corporation	04/2020
1143	XIMINO	Extended- release Capsules	90 mg	Journey Medical Corporation	04/2020
1144	XIMINO	Extended- release Capsules	135 mg	Journey Medical Corporation	04/2020
1145	XOPENEX	Inhalation Solution	0.31 mg/3 mL	Oak Pharmaceuticals, Inc.	08/2012
146	XOPENEX	Inhalation Solution	1.25 mg/3 mL	Oak Pharmaceuticals, Inc.	08/2012
1147	XOPENEX	Inhalation Solution	0.63 mg/3 mL	Oak Pharmaceuticals, Inc.	08/2012
1148	YASMIN	Tablets	3 mg; 0.03 mg	Bayer HealthCare Pharmaceuticals Inc.	05/09/2008
1149	ZANAFLEX	Capsule	6 mg	Covis Pharma GmbH	10/2011

	<b>Proprietary Name</b>	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
	ZANAFLEX	Capsule	4 mg	Covis Pharma GmbH	10/2011
	ZANAFLEX	Capsule	2 mg	Covis Pharma GmbH	10/2011
1152	ZARONTIN	Capsules	250 mg	Parke-Davis Division of Pfizer Inc.	10/12/2015
1153	ZAROXOLYN	Tablets	2.5 mg	Lannett Company, Inc.	10/2018
1154	ZAROXOLYN	Tablets	10 mg	Lannett Company, Inc.	10/2018
1155	ZAROXOLYN	Tablets	5 mg	Lannett Company, Inc.	11/2002 - 10/2003
1156	ZAVESCA	Capsules	100 mg	Actelion Pharmaceuticals Ltd.	04/2018
1157	ZEBETA	Tablets	5 mg	Lederle Laboratories	08/2000 - 08/2001
1158	ZEBETA	Tablets	10 mg	Lederle Laboratories	08/2000 - 08/2001
1159	ZEGERID	Capsules	20 mg/1100 mg	Salix Pharmaceuticals, Inc.	02/27/2006
1160	ZEGERID	Capsules	40 mg/1100 mg	Salix Pharmaceuticals, Inc.	02/27/2006

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1161	ZEGERID	Powder for Oral Suspension	40 mg/1680 mg	Salix Pharmaceuticals, Inc.	06/2014
	ZEGERID	Powder for Oral Suspension	20 mg/1680 mg	Salix Pharmaceuticals, Inc.	06/2014
1163	ZEMPLAR	Capsules	1 mcg	AbbVie Inc.	03/2014
	ZEMPLAR	Capsules	2 mcg	AbbVie Inc.	03/2014
	ZENPEP	Delayed Release Capsules	5000 lipase USP units	Eurand Pharmaceuticals, Ltd.	12/2/2009
1166	ZIAC	Tablets	2.5 mg; 6.25 mg	Teva Branded Pharmaceutical Products R&D, Inc.	08/2019
1167	ZIAC	Tablets	5 mg; 6.25 mg	Teva Branded Pharmaceutical Products R&D, Inc.	08/2019
1168	ZIAC	Tablets	10 mg; 6.25 mg	Teva Branded Pharmaceutical Products R&D, Inc.	08/2019
1169	ZIANA	Gel	1.2% and 0.025%	Bausch Health US, LLC	09/2020
1170	ZITHROMAX	Powder for Oral Suspension	300 mg (15 mL when mixed)	Pfizer Inc.	02/01/2005

	<b>Proprietary Name</b>	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1171	ZITHROMAX	Powder for Oral Suspension	600 mg (15 mL when mixed)	Pfizer Inc.	02/1/2005
172	ZITHROMAX	Powder for Oral Suspension	900 mg (22.5 mL when mixed)	Pfizer Inc.	02/01/2005
173	ZITHROMAX	Powder for Oral Suspension	1 gram (single dose packet)	Pfizer Inc.	2/1/2005
174	ZITHROMAX	Powder for Oral Suspension	1200 mg (30 mL when mixed)	Pfizer Inc.	02/01/2005
175	ZITHROMAX	Tablets	250 mg	Pfizer Inc.	02/01/2005
176	ZOLOFT	Oral Concentrate	20 mg/mL	Upjohn US 1 LLC	03/20/2006
177	ZOLOFT	Tablets	25 mg	Upjohn US 1 LLC	03/20/2006
178	ZOLOFT	Tablets	50 mg	Upjohn US 1 LLC	03/20/2006
179	ZOLOFT	Tablets	100 mg	Upjohn US 1 LLC	03/20/2006
1180	ZONALON and PRUDOXIN	Cream	5%	Mylan Pharmaceuticals, Inc.	01/2019
181	ZORIVAX	Cream	5%	Bausch Health US, LLC	08/2019
182	ZOVIRAX	Ointment	5%	Bausch Health US, LLC	04/2014
183	ZOVIRAX	Oral Suspension	200 mg per 5 mL	Mylan Pharmaceuticals Inc., a Viatris Company	10/2018
1184	ZYCLARA	Cream	3.75%	Bausch Health US, LLC	08/2018

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1185	ZYCLARA	Cream	3.75%	Bausch Health US, LLC	07/2020
1186	ZYFLO CR	Extended- release Tablets	600 mg	Chiesi USA, Inc.	04/2017
1187	ZYMAXID	Ophthalmic Solution	0.5 %	Allergan Sales, LLC	04/2015
1188	ZYTIGA	Tablets	250 mg	Janssen Biotech, Inc.	11/2018
1189	ZYVOX	Oral Suspension	100 mg/5 mL	Pharmacia and Upjohn Company	12/2015
1190	ZYVOX	Tablets	600 mg	Pharmacia and Upjohn LLC	12/2015